A Pilot Randomised Controlled Trial Examining the Feasibility, Acceptability and Potential Efficacy of Transdiagnostic CBT for Depression and Anxiety in Older People.

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Main Research Project &
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I wish to dedicate this thesis to the memory of Brenda Bridget Tuck, my grandmother, who passed away in December 2009 before learning that I succeeded in my quest to get on to clinical training, for which she would have been very proud. She was a strong and quirky woman, who I feel blessed to have known and miss dearly.

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Main Research Project:

A Pilot Randomised Controlled Trial Examining the Feasibility, Acceptability and Potential Efficacy of Transdiagnostic CBT for Depression and Anxiety in Older People.

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1. Abstract

Introduction: Anxiety and depression represent a common problem in later life and a growing challenge to society as the proportion of older people continues to rise. Despite this, the efficacy of evidence-based treatments to treat these disorders in older people has received little attention compared to working-age and youth populations. The current study examined the preliminary outcomes, feasibility and acceptability of a 12-session transdiagnostic Cognitive Behaviour Therapy (tCBT) intervention for older adults with symptoms of anxiety and depression.

Methods: 16 older adults (aged 60 and above) were randomised to either an immediate (n=8) or 7-week delayed tCBT treatment condition (n=8). Change scores on the HADS (Hospital Anxiety and Depression Scale) and CORE-10 (Clinical Outcomes of Routine Evaluation-10) were used to evaluate efficacy; rates of attrition due to practical reasons were used to evaluate the feasibility of the intervention; and rates of attrition due to treatment dissatisfaction, homework compliance and feedback from a Discharge Satisfaction Questionnaire were used to evaluate the acceptability of the intervention.

Results: Significant reductions in self-reported symptoms of anxiety and depression were reported pre- to post-treatment. Seventy-one percent of participants were classifiable as 'reliably improved' (n=10) and 64% as 'recovered' (n=9) in terms of their depression symptoms. Forty-three percent of participants were classifiable as 'reliably improved' (n=6) and 36% (n=5) as 'recovered' in terms of their anxiety symptoms following the intervention. Significant between-group differences were found in terms depression, but not anxiety symptoms. Satisfaction with the intervention and homework compliance was high, whilst rates of attrition low (n=3).

Discussion: Preliminary data suggest that this burgeoning approach can produce efficacious outcomes for older people with comorbid emotional disorders, and it is both feasible and acceptable to apply tCBT interventions to older people. tCBT has the potential to address

some of the shortcomings of disorder-specific CBT, through offering a more clinically and time-efficient approach to comorbidity and enabling much-needed improvements to the dissemination of and access to evidence-based psychological therapies for older people.

2. Introduction

2.1 Epidemiology and diagnosis of mood disorders in older people

Epidemiological studies reveal that rates of major depression (9.4%; Battaglia, Dubini, Mannheimer, & Pancheri, 2004) and anxiety disorders (15.3%; Kessler et al., 2005) are high among community-dwelling older people, and rise to 18% and 29% respectively when clinically significant sub-threshold symptoms are considered (O'Regan, Cronin & Kenny, 2013). Furthermore, these conditions frequently co-occur leading to increased symptom severity and disability (Angst et al., 1990). A large community study examining over 3000 55 to 85 year-olds revealed that almost half (47.5%) of those with a major-depressive disorder also met criteria for an anxiety disorder, and approximately a quarter (26.1%) with an anxiety disorder also met criteria for a depressive disorder (Beekman et al., 2000). These disorders therefore represent a common problem in later life, and pose a growing challenge and cost to society as the proportion of older people continues to rise.

Unfortunately, these disorders often go undetected in older people (Wolitzky-Taylor et al., 2010) due to differences in the way they manifest, which can mask or be misattributed to other types of difficulties. Firstly, compared to working-age people, older people with depression and/or anxiety tend to present with more somatic (e.g. apathy, fatigue, difficulty sleeping) and cognitive (e.g. poor memory and concentration) symptoms than affective symptoms (Alexopolous et al., 2002). Secondly, comorbid physical health conditions and chronic pain are especially common in older people, and it can be difficult to separate which somatic complaints are a product of these conditions, medication side effects or indicate an underlying emotional disorder. Thirdly, the higher incidence of cognitive impairment in this cohort also presents a challenge as the agitation and memory impairments typical of a Dementia diagnosis are also

noted in older people with emotional disorders. These nuances in presentation coupled with the tendency for older people to minimise and use different language to describe their symptoms (Lenze & Wetherell, 2011) increase the risk of these disorders being undetected and therefore untreated in older people. Moreover, emotional disorders in older people are associated with poorer wellbeing, and greater self-neglect, suicide, disability, chronicity and health-care utilisation than younger people with these disorders (de Beurs et al., 1999; Conway & Thompson, 2008; Schulz et al., 2000; Mitchell & Subramaniam, 2005). Therefore, it is imperative that the efficacy of evidence-based treatments is specifically examined among older people so that effective treatment options can be developed and made accessible to older people with these disorders. The next section summarises recent research examining the efficacy of Cognitive Behavioural Therapy (CBT) for older people with emotional disorders.

2.2 CBT for older people

Disorder-specific CBT (e.g. focussed on either depression or a specific anxiety disorder) is the recommended psychological intervention for targeting anxiety and depression in adults of all ages (NICE, 2007, 2009). This recommendation is mainly based on evidence from randomised controlled trials (RCTs) with working-age people, which have then been extrapolated to older people (Gould, Coulson & Howard, 2012a). However, it is important not to assume that this evidence is applicable to older people as there are several unique factors that are implicated in the aetiology and maintenance of these disorders in older people (see section 2.10), which may differentially impact treatment response (Alexopoulos & Bruce, 2009). Recent meta-analyses suggest that whilst disorder-specific CBT approaches are effective at alleviating anxiety and depression in older people when compared to non-active controls such as treatment as usual (TAU) or being on a waiting list, they achieve negligible (for depression) or only small effect sizes (for anxiety) when compared to active controls such as psychoeducation (Gould et al., 2012a; Gould,

Coulson & Howard, 2012b). Gould et al (2012b) suggest that this finding may have arisen because most RCTs with older people have tended to use non-active rather than active controls and the quality of these studies has varied considerably, both of which could hamper the magnitude of the effect sizes. Together these reviews suggest that disorder-specific CBT approaches may be less effective for treating these conditions in older people than working-age people. This highlights the danger of extrapolating findings to older people and the need to investigate alternative treatment approaches that could be used instead, or to enhance the efficacy of CBT approaches in older people. Gould et al. (2012b) argue that given that anxiety and depression are highly comorbid among older people, transdiagnostic interventions, which explicitly target comorbidity, may improve therapeutic outcomes for older people with these conditions. The next section outlines the shortcomings of using a disorder-specific approach relative to the advantages of using a transdiagnostic CBT approach for older people with emotional disorders.

2.3 The shortcomings of disorder-specific CBT versus the advantages of tCBT

Until recently, researchers have focussed on identifying the constructs that are distinct and specific to separate psychological disorders. This focus has generated a plethora of different CBT protocols to treat specific emotional disorders such as social anxiety disorder (SAD; Clark & Wells, 1995), obsessive-compulsive disorder (OCD; Salkovskis, Richards & Forrester, 1998), body dysmorphic disorder (BDD; Veale & Neziroglu, 2010), panic disorder (PD; Clark, 1986), and posttraumatic stress disorder (PTSD; Ehlers & Clark, 2000). However, this traditional, disorder-specific CBT approach has several shortcomings and does not yet demonstrate sufficient efficacy for the treatment of emotional disorders in older people. Therefore, alternative approaches warrant attention. tCBT is one such alternative approach and can be used to help people experiencing more than one type of disorder (e.g. depression and anxiety). tCBT

treatment adopts an integrative, empirical approach and does not rely on diagnostic assessment and exclusivity. Rather it focuses on and targets the cognitive, behavioural and physiological processes that are shared across different disorders (Harvey, Watkins, Mansell, & Shafran, 2004). A tCBT approach was first developed for the treatment of eating disorders (Fairburn, Shafran & Cooper, 2003), but has since been developed for the treatment of diverse emotional disorders (Barlow et al., 2011). tCBT has the potential to address some of the shortcomings of disorder-specific CBT for older people. These are discussed in further detail below.

2.3.1 Tackling comorbidity

Diagnostic comorbidity represents an important clinical challenge for clinicians as individuals with comorbid diagnoses often report greater symptom severity and disability than those with a single diagnosis (Angst et al., 1990) and "at present there is little empirical evidence to guide healthcare professionals or patients in choosing which disorder should be treated first" (NICE CG 123, p38). Therefore it is timely to evaluate the effectiveness of transdiagnostic approaches, which tackle anxiety and depression symptoms concurrently as these could provide a clear treatment alternative where comorbidity exists.

Whilst disorder-specific CBT protocols have demonstrated some benefit to patients with comorbid emotional disorders (Borkovec, Abel & Newman, 1995; Tsao, Mystkowski, Zucker & Craske, 2002; Brown, Antony & Barlow, 1995) the majority of patients retain their comorbid diagnoses at post-treatment, and where these are relieved high levels of sub-threshold symptoms are often reported (Corominas, Guerrero & Vallejo, 2002). Furthermore, research suggests that post-treatment reductions in comorbid diagnoses achieved using a disorder-specific CBT approach are associated with a higher likelihood of relapse (Borkovec et al., 1995; Brown et al., 1995). One explanation for why disorder-specific CBT protocols appear to achieve only a temporary

impact on comorbid diagnoses is perhaps due to the priority this approach gives to targeting the overt and diagnostic-exclusive maintaining processes over those that are latent and shared. Suggestions to improve outcomes for those with comorbid emotional disorders include, applying different disorder-specific CBT protocols sequentially or simultaneously to relieve broad-spectrum symptoms. However, neither of these options is attractive as sequential application is time-consuming and costly, and simply combining different disorder-specific protocols has been shown to dilute their efficacy. For instance, Craske et al. (2007) demonstrated that participants with PD were more likely to achieve HESF at post-treatment, and report no panic attacks at the 1-year follow-up when they received CBT focussed solely on PD rather than CBT, which attempted to amalgamate techniques without any underlying theoretical basis.

On the other hand, transdiagnostic treatment protocols have the potential to enhance therapeutic outcomes for individuals with comorbid disorders. It is possible that a transdiagnostic approach may improve time- and cost-effectiveness as it addresses common maintaining processes using techniques relevant across the emotional disorders, although this has not yet been examined. Given that older people demonstrate such high rates of emotional comorbidity, it is therefore of particular interest to examine the feasibility, acceptability and efficacy of a transdiagnostic approach within this population.

2.3.2 Tackling sub-threshold symptoms

Sub-threshold and non-standard presentations of emotional disorders such as those falling within the 'not otherwise specified' (NOS) categories also represent a common challenge to clinicians (McManus, Shafran & Cooper, 2010). This issue is particularly pertinent to clinicians working with older people, who are less likely to meet full criteria for these disorders than working-age people

(Byers et al., 2010), perhaps due to the presentation differences noted previously (language, increased somatic complaints, cognitive impairment). There is little research evidence available to guide how to treat these non-standard presentations apart from a single case study documented by Shafran, McManus & Lee (2008). Shafran et al. (2008) achieved success when using a tCBT approach to treat a working-age client with anxiety disorder NOS, and argued that (in line with the eating disorders literature; Fairburn et al., 2007), NOS categories may be better served by tCBT rather than disorder-specific protocols, because tCBT relies less on diagnostic accuracy and specificity to guide the focus of treatment.

2.3.3 Improving dissemination and access

The drive to define the specific features and mechanisms of different disorders has resulted in an unwieldy array of disorder-specific CBT protocols, which can be confusing for clinicians. For instance, Wilamowska et al. (2010) point out that there are more than 15 published protocols for PD alone, which contain only minor variations and no explanation of what protocol to apply with which type of client. The proliferation of disorder-specific CBT protocols has also led to inefficiency in training (since this is required for each protocol [Clark, 2009]). This emphasis on disorder-specific protocols has therefore substantially hindered the dissemination of evidence-based treatments and thus the public's access to them (McHugh & Barlow, 2010). Older people in particular, experience great difficulty accessing psychological therapies (Ghosh, 2009). For instance, a recent Department of Health (DoH; 2011) document reported that on average older people only represented 4% of those accessing IAPT (Improving Access to Psychological Therapies) services, whereas the age profile of the population and the prevalence of depression and anxiety disorders within this age group suggest this should be closer to 12%. In contrast tCBT, which offers a more succinct and widely applicable approach, could improve the dissemination of and access to evidence-based psychological therapies for older people.

2.3.4 Summary

tCBT has the potential to address some of the shortcomings of disorder-specific CBT for older people, through offering a more efficient and potentially efficacious approach to comorbidity and non-standard presentations. This in turn would likely enable much needed improvements to the dissemination of and access to evidence-based treatment of anxiety and depression for older people. The next section further considers the empirical rationale for utilising a tCBT rather than disorder-specific approach for the treatment of emotional disorders. Key evidence highlighting the significant overlap between these disorders is reviewed from 4 main bodies of research.

2.4 The overlap between emotional disorders

2.4.1 Evidence of diagnostic overlap

The frequent co-occurrence of anxiety and depression is the foremost indicator of diagnostic overlap among the emotional disorders (Beekman et al., 2000; Kessler et al., 2005). Another strong indicator lies in the apparent lack of treatment specificity resulting from pharmacological (Bandelow et al., 2002) and psychological interventions. For example, disorder-specific CBT treatment targeting one anxiety disorder has been shown to reduce other comorbid anxiety disorders and depression. Borkovec et al. (1995) reported that following CBT for GAD (Generalised Anxiety Disorder), 48% of participants no longer met criteria for a comorbid anxiety or depression diagnosis. Similarly, studies delivering CBT for PD noted that rates of comorbid emotional disorders reduced by 57% (Tsao et al., 2002; Brown et al., 1995). These findings have been replicated in a recent meta-analysis of CBT for anxiety disorders in older people where reductions were achieved in comorbid depression symptoms as well as anxiety symptoms (Gould et al., 2012b). This striking evidence of diagnostic overlap between the emotional disorders lends support

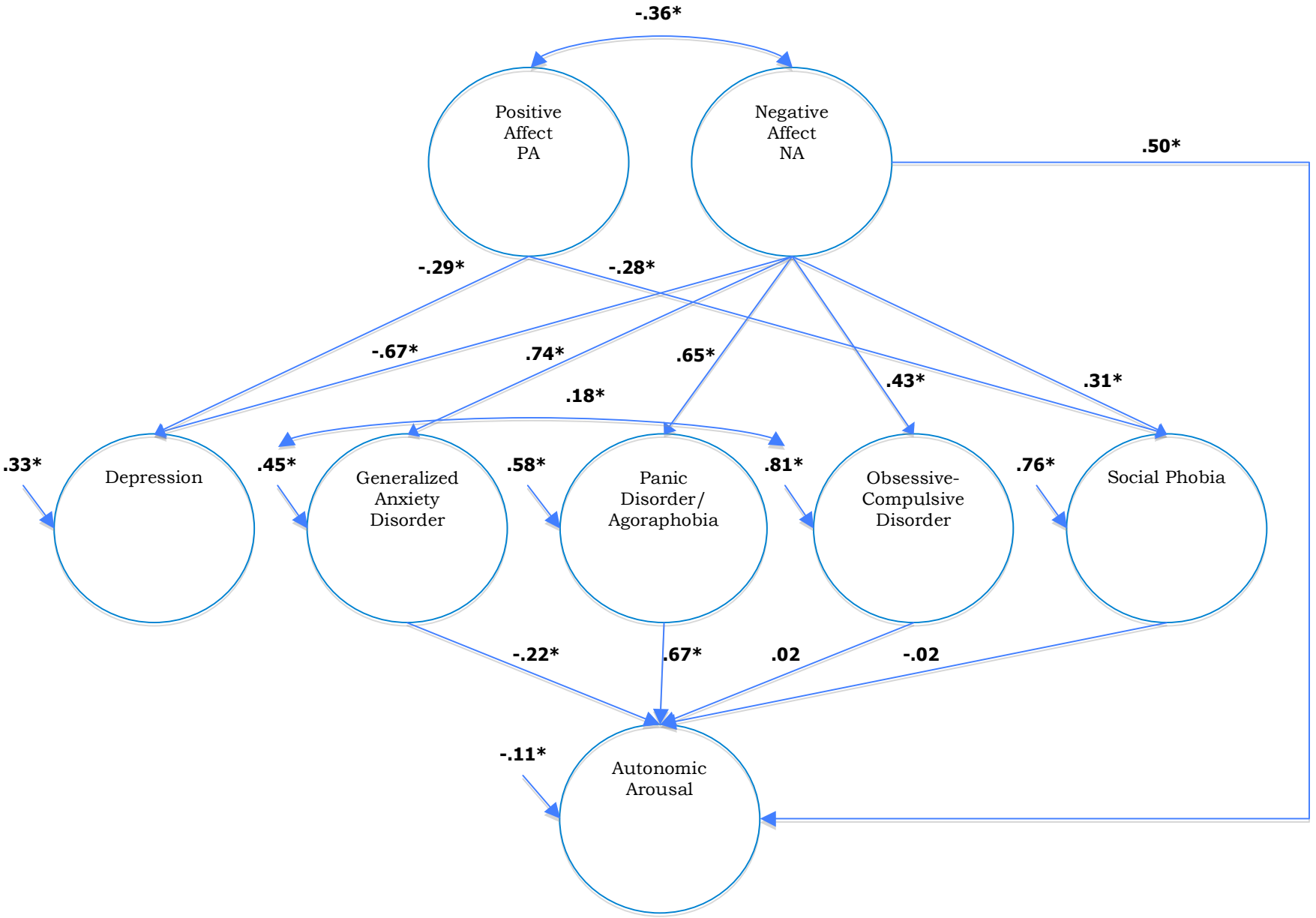
to the notion that taking a transdiagnostic approach to the formulation and treatment of emotional disorders may be more pragmatic.

2.4.2 Evidence of a shared underlying structure

There is also extensive evidence to support the notion of a common underlying structure to emotional disorders, which plays a key role in their onset, trajectory and maintenance. Clark and Watson's (1991) 'tripartite' model of emotional disorders posits that three factors: high 'negative affectivity' (NA; e.g. fear, hatred), low 'positive affectivity' (PA; e.g. enthusiasm) and high 'physiological hyperarousal' (PH; e.g. racing heart, dizziness) can explain the specific and shared elements of anxiety and depression. More specifically Clark and Watson (1991) argue that depression is epitomised by high NA and low PA, anxiety by high NA and high PH, and comorbid depression and anxiety as high NA, low PA and high PH. Research using structural equation modelling to examine the factor structure of emotional disorders has validated these shared higher-order factors among samples of adults (Brown, Chorpita & Barlow, 1998) and young people with these disorders (Chorpita, Albano & Barlow, 1998). For example Brown et al. (1998) employed a large outpatient sample (n=350) of adults with anxiety and depression to examine the structural relationships of various emotional disorders (depression, GAD, SAD OCD, PD) and confirmed a hierarchical structure (see Figure 1). In this model, 'negative affect' and 'positive affect' emerged as higher-order factors, with significant paths from 'negative affect' to each of the 5 emotional disorders (depression, GAD, PD/AG, OCD, SAD) and significant paths from 'positive affect' to depression and SAD only. 'Autonomic Arousal' (or Physiological Hyperarousal) emerges as a lower-order factor with significant paths from PD/AG and GAD. This important study indicates that although the key features of emotional disorders cannot be collapsed indiscriminately into a single syndrome, the similarities between these disorders outweigh the differences. Therefore, a transdiagnostic treatment approach such as tCBT, which

targets the shared (negative and positive affect), rather than specific latent structures of emotional disorders may be more efficient and meaningful.

Figure 1: Brown, Chorpita and Barlow's (1998) Structural model of interrelationships between DSM-IV emotional disorders.



2.4.3 Evidence of a shared aetiology

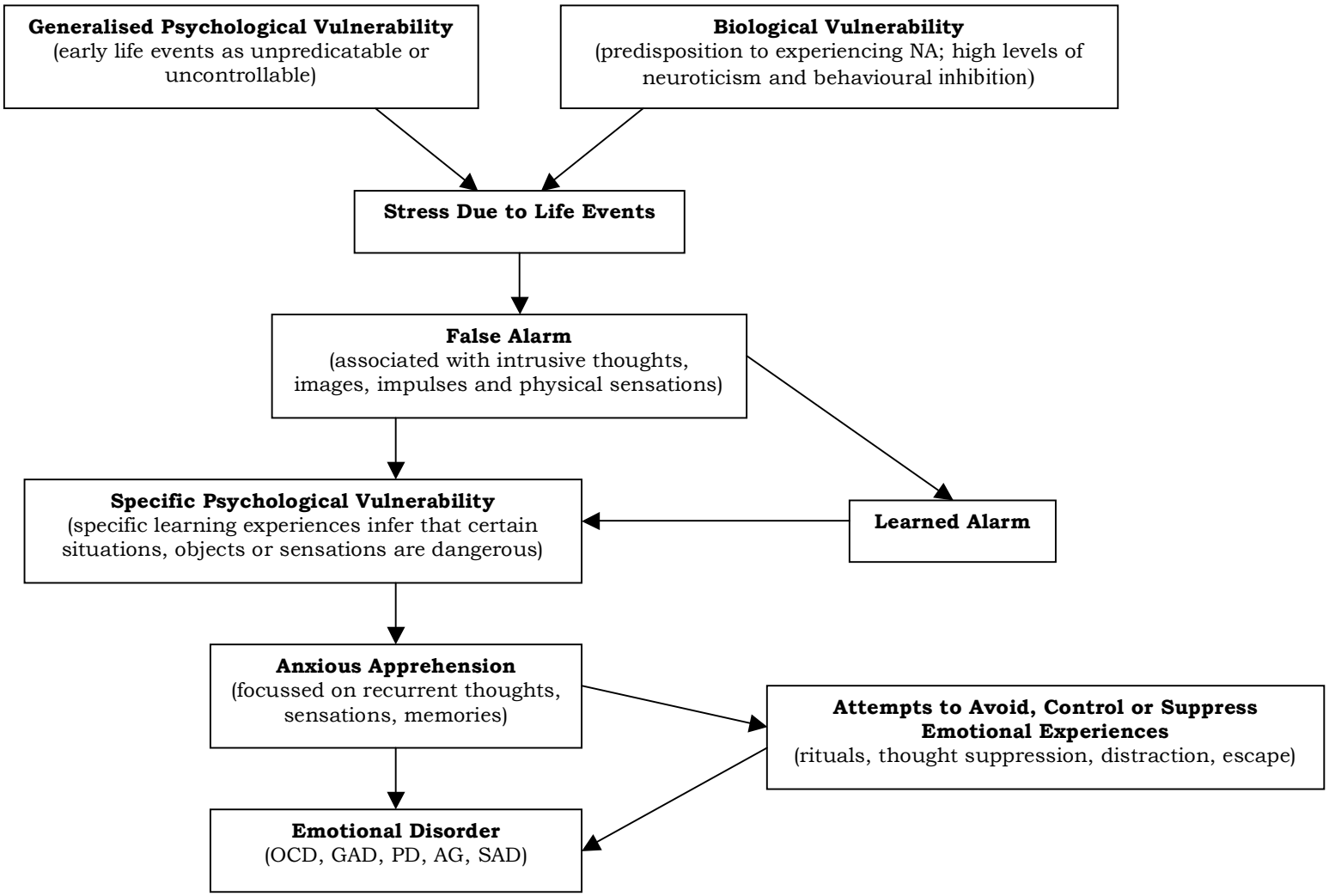
Barlow's (2002) triple vulnerability model of emotional disorders proposes that these disorders have a shared aetiology. The model asserts that individuals are at increased risk of experiencing anxiety and depression in the face of stressful life events if they possess 'generalised' biological and psychological vulnerabilities. Barlow's (2002) so called 'generalised biological vulnerability' refers to the significant genetic contribution (approximately 30-50% of the variance) seen in the development of emotional disorders. Meanwhile Barlow (2002) proposes that a 'generalised psychological vulnerability' develops in childhood in the context of a stressful and unpredictable early environment. These early experiences are believed to undermine the child's self-efficacy and development of adaptive coping strategies, leading them to perceive a general lack of controllability and predictability over life events. A third 'specific psychological vulnerability' factor can then be generated if a child is exposed to specific learning experiences, which for example teach the child that certain situations, objects or sensations are dangerous. Therefore, whilst the two general vulnerabilities are thought to create a non-specific anxious temperament, if paired with the third 'specific psychological vulnerability' these are believed to give rise to disorder specific variations such as SP, SAD and PD (Barlow, 2002). A strength of this model is that it explains how both commonalities and differences may arise among the emotional disorders.

Boisseau et al. (2010) have built upon Barlow's (2002) triple vulnerability model to create a unified perspective of the origin of emotional disorders, which incorporates several key transdiagnostic factors that have emerged in the literature (see section 2.5 for a discussion of these). This UP model (see Figure 2) depicts how the shared aetiology underlying emotional disorders can explain how these disorders emerge and why a transdiagnostic treatment approach is therefore appropriate.

The model focuses on how those with emotional disorders process and respond to emotional experiences. It suggests that a biological predisposition to experiencing NA and behavioural inhibition combine with uncontrollable early life events to create persistent 'stress' when confronted with certain life events. This 'stress' is likened to an alarm where aversive thoughts and physical sensations are experienced and signal danger. Barlow (2002) argues that through a process of interoceptive conditioning these events can become associated with intense, recurrent and uncontrollable emotional experiences, which serve as additional 'evidence' of the presence of threat. As a result attempts to control, reduce, avoid or suppress negative affect and physiological arousal emerge (e.g. thought suppression, distraction, escape, rituals, safety behaviours). From a transdiagnostic perspective then, the interpretations made about initial emotional experiences (i.e. dangerous, uncontrollable) and the attempts to avoid or control these emotional experiences become the targets for intervention.

It is important to note that this model was not designed to be used with clients for the purpose of formulation and does not feature in the UP workbook and treatment manual. However, a description of how the 'three-component model of emotional experiences' is used to highlight with clients the physiological, cognitive and behavioural aspects of emotion that will become the targets of treatment and how this might be adapted to incorporate the conceptual adaptations relevant to older people is discussed in section 2.10.3.

Figure 2: UP model of the origin of emotional disorders (Boisseau et al., 2010)



2.4.4 Evidence of neurobiological overlap

Neuroimaging research has also provided support for the existence of an overarching syndrome. For instance, some studies have found that participants with anxiety and depressive disorders could be distinguished from matched healthy controls by more intense activity in the limbic structures, coupled with impaired inhibitory control within the cortical structures (Mayberg et al., 1999; Etkin & Wager, 2007). More specifically, several neuroimaging studies have noted a trend of increased amygdala activation, together with impaired cortical inhibition of amygdala responses among participants with SAD (Tillfors, Furmack, Marteinsdottir & Fredrikson, 2002; Lorberbaum et al., 2004; Phan, Fitzgerald, Nathan & Tancer, 2006), GAD (Hoehn-Saric, Schlund & Wong, 2004; Paulesu et al., 2010), PTSD (Shin et al., 2005), SP (Specific Phobia; Paquette et al., 2003; Straube et al., 2006) and depression (Goldapple et al., 2004; Siegle et al., 2007). Taken together, these findings could help account for why individuals with emotional disorders present with more intense and frequent negative emotional experiences.

2.4.5 Summary of overlap between the emotional disorders

To summarise, research documenting consistent patterns in the underlying structure, aetiology, neuroactivation and co-occurrence of emotional disorders, provides evidence of a considerable overlap between anxiety and depression. Furthermore, this evidence suggests that moving away from a focus on the differences to the similarities between these disorders may be a more fruitful approach to their formulation and treatment. The high rate of overlap documented among emotional disorders has led to a search for so called 'transdiagnostic' factors, which may play a common role in their aetiology and maintenance.

2.5 Transdiagnostic factors

2.5.1 Attention

Harvey, Watkins, Mansell and Shafran (2004) propose that selective and self-focussed attention can be regarded as transdiagnostic cognitive processes. Selective attention can be defined as the prioritisation of certain stimuli within one's internal or external environment, and when an individual consistently attends to a specific type of stimuli this is referred to as an attentional bias. Studies using an emotional Stroop task with individuals with a range of anxiety (GAD: Mathews & MacLeod, 1985; SAD and PD: Hope, Rapee, Heimberg & Dombeck, 1990) and depressive (Gotlib & Cane, 1997) disorders reliably demonstrate a Stroop effect (attentional bias) for words that relate to their concerns. Likewise, studies using a dot-probe paradigm have found consistently shorter reaction times when individuals with a range of affective disorders are presented with threat-related stimuli relative to neutral stimuli (Bar-Haim et al., 2007). This body of research lends support to the notion that selective attention towards concern-related stimuli is a transdiagnostic process across the emotional disorders.

Self-focussed attention can be defined as the tendency to attend to internal (e.g. physical sensations, thoughts, emotions, memories, images) as opposed to external stimuli. This type of attention is already explicitly highlighted as a key treatment target in CBT models for SAD (Clark & Wells, 1995) and BDD (Veale & Riley, 2001). However, Woodruff-Borden, Brothers and Lister (2001) found the tendency to engage in self-focussed attention is also shared amongst individuals with depression, PD and several other anxiety disorders. Furthermore, Woodruff et al. (2001) report that greater self-focussed attention was predictive of more distress and impairment, which would indicate that reducing self-focussed attention is likely to be a beneficial treatment target across the emotional disorders.

2.5.2 Memory

There is considerable evidence to indicate that two particular memory processes are consistently elevated across the emotional disorders. The first is an explicit selective memory bias, which is where individuals tend to consciously retrieve previously presented stimuli relevant to their concerns. Radomsky and Rachman (1999) examined this memory bias among participants with and without OCD. Participants were asked to watch whilst the experimenter touched various objects with either a 'clean' or 'contaminated' tissue and found that those with OCD demonstrated a superior recall for the objects, which had been 'contaminated'. In two similar studies Lundh and Ost (1996) and Lundh, Thulin, Czyzykow and Ost (1998) also demonstrated this memory bias among participants with SAD and PD. Participants with and without these conditions were presented with a series of faces and asked to rate which were critical versus accepting (SAD) or safe versus unsafe (PD). In both studies participants in the clinical group demonstrated a memory bias for faces related to their current concern (e.g. critical faces; SAD, safe faces; PD). Clark and Teasdale (1982) also compared this memory bias among individuals with depression. Participants were asked at times when they were feeling particularly depressed and less depressed to recount past experiences to a series of neutral words. The authors found a mood-congruent memory bias where unhappy memories were more likely to be retrieved when participants were feeling down, and happy memories were more likely to be retrieved when participants were feeling less down.

The second transdiagnostic memory process to emerge across the emotional disorders is recurrent intrusive memories (Holmes & Hackmann, 2004). Again, the content of these typically relate to the specific concerns of each disorder. For instance, Reynolds and Brewin (1999) asked participants with either PTSD or depression to recount stressful life events, which had triggered intrusive memories. Overall, the intrusive memories experienced within these disorders appeared

to be similar, except for their content where for participants with PTSD these were prompted by personal illness or assault, and for those with depression these tended to be preceded by negative interpersonal events such as bereavement or family illness. Intrusive memories have likewise been implicated in the development and maintenance of various other emotional disorders including SAD (Hackmann, Clark, & McManus, 2000), agoraphobia (AG; Day, Holmes, & Hackmann, 2004), OCD (Speckens, Hackmann, Ehlers, & Cuthbert, 2007) and health anxiety (HA; Muse et al., 2010). Altogether these findings provide robust evidence to suggest that certain memory processes occur similarly across emotional disorders and may go some way to accounting for their development and persistence.

2.5.3 Recurrent negative thinking

'Recurrent negative thinking' (RNT) is a common feature of many psychological disorders, and has been shown to be a common risk factor to the development of several anxiety and depressive disorders (Ruscio et al., 2011), suggesting it may be a transdiagnostic phenomenon (Harvey et al., 2004). Rumination and worry represent two main forms of RNT and are highly correlated with one another (Fresco et al., 2002). Rumination can be defined as a pattern of negative thinking in which a person passively and repeatedly dwells on the causes and consequences of debilitating symptoms without active attempts to alleviate this distress (Nolen-Hoeksema & Morrow, 1991). Examples tend to include 'Why' type questions (e.g. Why did this happen to me?). Worry on-the-other-hand can be defined as 'a chain of thoughts and images, negatively-affect laden and relatively uncontrollable' (Borkovec, Robinson, Puzinsky & DePree, 1983, p. 10). Examples of worry tend to include 'What if' type questions (e.g. What if I lose my job?). Watkins (2008) suggests that the only distinction between these two forms of RNT is the temporal focus with rumination being more past-orientated and worry more future-orientated.

McEvoy, Watson, Watkins and Nathan (2013) further scrutinised RNT as a transdiagnostic construct by investigating the extent to which RNT could account for the high rates of comorbidity observed between the emotional disorders. The authors compared levels of worry and rumination among individuals with (n=301) and without (n=212) comorbid anxiety and depressive disorders in the community. McEvoy et al. (2013) found that individuals with and without comorbidity demonstrated equivocal levels of worry and rumination, irrespective of their primary diagnosis, and inline with the transdiagnotic hypothesis, higher levels of RNT were associated with increased likelihood of comorbidity. These findings suggest that RNT represents an important treatment target, across the emotional disorders, and is supported by the finding that CBT targeting RNT achieves reductions in self-reported worry, rumination, anxiety and depression (Watkins et al., 2007, 2011).

2.5.4 Cognitive reasoning biases

Harvey et al. (2004) propose that interpretative and expectancy reasoning biases can be regarded as 'definite' transdiagnostic processes (occurring in 4 or more emotional disorders). Based on this evidence the UP (Barlow et al., 2011) focuses on addressing two common forms of reasoning bias (or 'thinking traps'), one interpretative – 'thinking the worst' (where the aversiveness and consequences of the event are exaggerated and one's ability to cope with it is underestimated) and one expectancy 'jumping to conclusions' (where the likelihood of the feared outcome occurring is greatly exaggerated).

An interpretative reasoning bias can be defined as the tendency to construe the meaning of ambiguous situations in a negative way, and among individuals with emotional disorders these negative interpretations tend to relate to their disorder-specific concerns (Harvey et al., 2004). For example, participants with depression

endorse more negative interpretations of ambiguous scenarios than healthy controls (Nunn, Mathews & Trower, 1997), participants with PD demonstrate an interpretative bias to ambiguous interoceptive stimuli (e.g. racing heart), which is absent in non-panic controls (Richards, Austin & Alvarenga, 2001), participants with SAD make more negative interpretations of socially ambiguous situations, relative to other ambiguous situations and participants with OCD (Amir, Foa & Coles, 1998), and participants with HA demonstrate a preference for illness rather than benign interpretations of physical sensations (Haenen et al., 2000).

An expectancy reasoning bias can be defined as the tendency to make negative predictions about future events, whilst ignoring the actual likelihood of a particular outcome occurring. Again the nature of the negative prediction tends to reflect the specific concerns of each disorder (Harvey et al., 2004). For example, there is evidence to suggest that participants with PD tend to overestimate the intensity of and likelihood they will panic in fear-inducing situations (Rachman & Lopatka, 1986), spider phobia tend to overestimate the likelihood of being bitten by a spider relative to controls (Jones & Menzies, 2000), SAD tend to overestimate the likelihood of future negative social (but not non-social) events occurring (Foa, Franklin, Perry & Herbert, 1996), HA tend to overestimate the risk of developing diseases (Haenen et al., 2000), and participants with depression tend to be more pessimistic when predicting future outcomes (Dunning & Story, 1991), make higher estimates regarding the likelihood of future negative future events occurring (Kaney, Bowen-Jones, Dewey & Bentall, 1997) and lower estimates regarding the likelihood of positive future events occurring (Anderson, Spielman & Bargh, 1992) relative to healthy controls.

2.5.5 Experiential avoidance

Experiential avoidance in all its behavioural and cognitive manifestations is perhaps the most striking and pervasive maintenance process noted across the emotional disorders (Brown & Barlow, 2009) and therefore represents an important treatment target.

Examples of experiential avoidance can include both avoiding external situations (which may trigger aversive consequences/emotions/physical sensations) and avoiding the internal experience of aversive states (e.g. through distraction, thought suppression and rumination). Whilst some forms of experiential avoidance may be more clearly observable (e.g. escaping a situation, avoiding eye contact) and maintained by negative reinforcement contingencies (taking away aversive stimuli) others such as carrying a mobile phone or water bottle (safety seeking behaviours) may be less obvious and maintained by positive reinforcement contingencies (addition of reassuring stimuli). Brown and Barlow (2009) provide a comprehensive overview of the various behavioural and cognitive forms of experiential avoidance, which can occur alongside the disorders these are commonly associated with (see Table 1).

Table 1: Summary of experiential avoidance strategies and the disorders often associated with (Brown & Barlow, 2009).

	Avoidance strategy	**Disorder often associated**
Situational avoidance/escape	- Avoidance/escape from phobic situations (e.g. crowds, public speaking, lifts, heights, animals, site of trauma).	SAD, PD, AG, PTSD, SP
Subtle behavioural avoidance	- Avoidance of 'contaminated' objects	OCD
	- Avoidance of eye contact	SAD
	- Avoidance of sensation-provoking stimuli (e.g. physical exertion, hot rooms, caffeine)	SAD, PD
	- Procrastination	DP, GAD
Cognitive avoidance	- Dissociation	PD, PTSD
	- Distraction	DP, GAD, PD, AG, SAD
	- Worry	GAD, SP, SAD, PD, OCD
	- Rumination	DP, OCD, PTSD
	- Thought suppression	All
	- Avoidance of aversive memories, imagery or thoughts	OCD, PTSD, PD, SAD, DP
Safety signals	- Carrying mobile phone, water bottle, medication	PD, AG, SAD
	- Holding on to good luck charm	OCD
	- Carrying self-protective objects	PTSD
	- Carrying reading material/notes	GAD, SAD

Notes: GAD = generalised anxiety disorder; SAD = social anxiety disorder; PD = panic disorder; AG = agoraphobia; PTSD = post-traumatic stress disorder; SP = specific phobia; AG = Agoraphobia; DP = depression; OCD = obsessive compulsive disorder; PTSD = posttraumatic stress disorder.

Salkovskis et al. (1999) demonstrated that participants with PD who dropped their safety behaviours (experiential avoidance strategies) during an exposure exercise reported less anxiety and conviction in their catastrophic cognitions than those who maintained their safety behaviours. The role of safety-behaviours in maintaining other emotional disorders such as BDD (Veale & Riley, 2001), OCD (Rachman, 2002), SAD, (Wells et al., 1995) and specific phobia (SP; Sloan & Telch, 2002) is also apparent.

2.5.6 Anxiety sensitivity

Anxiety sensitivity (AS) can be defined as a specific fear of anxiety-related bodily sensations due to beliefs that such sensations are dangerous and will lead to catastrophic outcomes such as physical illness or public humiliation (Reiss, Peterson, Gursky, & McNally, 1986). Although AS (a form of state anxiety) is related to trait anxiety (the general tendency to experience anxiety symptoms across a wide variety of stressful situations) the two constructs are empirically and conceptually distinct (McNally, 1996).

AS has traditionally been linked with PD, however, there is mounting evidence to suggest that AS is implicated in the development and maintenance of several emotional disorders (Naragon-Gainey, 2010; Schmidt, Zvolensky & Maner, 2008). Most recently Boswell et al. (2013) combined outcome data from two recent trials of the UP (Ellard et al., 2010; Farchione et al., 2012) to examine levels of AS across four anxiety disorders; OCD, GAD, PD and SAD (n=54). The authors reported that all participants demonstrated moderate to high levels of AS at pre-treatment, and participants with comorbid anxiety disorders indicated the highest levels of AS. Furthermore, multiple regression analyses revealed that large reductions in AS during treatment were associated with reductions in diagnostic severity at post-treatment and 6-month follow-up.

AS has also been found to be elevated in individuals with depression when compared to healthy controls (Otto et al., 1995). Taylor, Koch, Woody and McLean (1996) examined this relationship further using factor analysis and demonstrated that AS is multidimensional and consists of 3 factors: (i) a fear of displaying publicly observable symptoms, (ii) a fear of losing cognitive control and (iii) a fear of bodily sensations. Taylor et al. (1996) analysed the relationships between these factors and depression-related symptoms to reveal that whilst factors (i) and (iii) were correlated with anxiety-related measures, factor (ii) appeared to represent a depression-specific form of AS,

which correlated with depression- but not with anxiety-related symptoms. Furthermore, Watt & Stewart (2008) demonstrated that when AS was specifically targeted in a 3-day CBT program symptoms of depression were effectively reduced alongside levels of AS. Together these results suggest that AS may be more accurately conceptualised as a transdiagnostic rather than diagnosis-specific construct, and represents an important target for change across a range of emotional disorders.

2.5.7 Perfectionism

A second temperamental construct is perfectionism, which has been defined as an "…overdependence of self-evaluation on the determined pursuit of personally demanding, self-imposed standards in at least one highly salient domain, despite adverse consequences" (Shafran, Cooper & Fairburn, 2002, p778). Perfectionism has been linked to the aetiology and maintenance of various disorders (Shafran & Mansell, 2001) including depression (Sassaroli et al., 2008) and anxiety disorders such as OCD, SAD and PD (Antony, Purdon, Huta & Swinson, 1998). Furthermore, in a sample of adults with anxiety and depression (n=345) Bieling, Summerfeldt, Israeli & Antony, (2004) found that the co-occurrence of these disorders was associated with increased scores on a robust measure of perfectionism (the Multidimensional Perfectionism Scale; Frost, Marten, Lahart, & Rosenblate, 1990).

Research has also indicated that if left untreated perfectionism can impact negatively on treatment outcomes for anxiety and depression. For instance, in a small sample of participants with SAD (n=24) Lundh and Ost (2001) found that treatment non-responders scored significantly higher on a self-report measure of perfectionism at pre-treatment. Similarly, Blatt, Quinlan, Pilkonis, & Shea (1995) found that high levels of perfectionism predicted poorer treatment outcomes at post treatment and 18-month follow-up (Blatt et al., 1998) among participants with depression. There are a number of potential

mechanisms through which the literature suggests that perfectionism may interfere here, including disrupting therapeutic alliances (Zuroff et al., 2000), and predicting a poorer ability to cope with life stressors and a restricted social network (Shahar et al., 2005). The culmination of evidence implicating perfectionism with various psychopathologies suggests that perfectionism is best conceptualised as a transdiagnostic process (Egan, Wade & Shafran, 2011).

2.5.8 Intolerance of uncertainty

Intolerance of uncertainty (IU) relates to the tendency to view potential future negative events as threatening and intolerable, irrespective of the actual probability of them occurring (Koerner & Dugas, 2008). IU is most commonly known to be a vulnerability factor for GAD (Laugesen, Dugas & Bukowski, 2003). However, a growing body of research suggests that this construct is associated with numerous other emotional disorders including OCD (Steketee, Frost & Cohen, 1998), PD (McEvoy & Mahoney, 2011), SAD (Carleton, Collimore, & Asmundson, 2010) and depression (Miranda, Fontes & Marroqui'n, 2008). McEvoy and Mahoney (2012) present evidence to suggest that IU partially mediates the association between neuroticism and symptoms of GAD, OCD, SAD, PD and depression. Mahoney and McEvoy (2012) examined the extent to which adults with anxiety and depression endorsed items on the Intolerance of Uncertainty Scale-12 (Carleton, Norton & Asmundson, 2007). Participants (n=218) were screened using the Anxiety Disorders Interview Schedule (ADIS) and 75% of the sample met criteria for 2 or more mood disorders. The results revealed higher levels of IU amongst those with comorbid versus single emotional disorders. Although further research is needed to clarify the causal links between IU and mood disorders, these findings suggest that IU may be better conceptualised as an important transdiagnostic maintaining factor (Starcevic & Berle, 2006).

2.5.9 Summary of transdiagnostic factors

Overall, this body of research proposes that there are several cognitive, behavioural and temperamental processes that may be considered 'transdiagnostic', which is in line with the idea that anxiety and depression have shared rather than distinct psychopathologies. Furthermore, these findings suggest that emotional disorders may be better addressed using a single rather than multiple set of therapeutic principles, which target common rather than distinct maintaining processes.

2.6 tCBT protocols

To date several independently developed tCBT protocols exist for the treatment of emotional type disorders (see Table 2 for a summary). The vast majority of these have been designed to be applied to heterogeneous anxiety disorders and be delivered in a group format (Erikson, 2003; Garcia, 2004; Larkin, Waller & Combs-Lane, 2003; Schmidt, 2003; Norton & Hope, 2005). However, more recently tCBT protocols aimed at both anxiety and depressive disorders have been developed (McEvoy & Nathan, 2007; Barlow et al., 2011) and delivered in computerised formats over the Internet (Anxiety Program, Titov et al., 2010; Wellbeing Program; Titov et al., 2011). This proliferation of tCBT protocols has led to a burgeoning of research interest and demonstrable utility in this area. The content and treatment emphasis of each tCBT protocol is briefly described in the next two sections (2.7 and 2.8) along with related research examining their efficacy. Section 2.9 then introduces Barlow et al.'s (2011) UP for emotional disorders, and presents its emerging empirical support together with the reasons why this protocol was selected for adaptation to an older, British audience in the current study.

2.7 tCBT protocols for anxiety disorders

2.7.1 Erikson's (2003) protocol

Erikson (2003) developed a 12-week, group tCBT protocol for participants with GAD, PD, AG, SAD and/or PTSD. Erikson (2003) examined the original protocol in an uncontrolled trial with participants with GAD, SAD, PD, AG and/or PTSD and achieved significant reductions on all self-reported measures of anxiety (Brief Symptom Inventory; Derogatis, 1993, Fear and General Symptom Questionnaire; Hallam & Hafner, 1978), which were maintained at 6-month follow-up. However, there were significant limitations to this uncontrolled study including an unrepresentative sample (76% female), and the uncontrolled use of concurrent psychotropic medication by 96% of the sample and the follow-up data being based on only 31% of the sample.

Erikson, Janeck and Tallman (2007) examined the efficacy of a revised version of this protocol for participants with any anxiety disorder except those 'NOS'. Erikson et al. (2007) randomly assigned 152 participants to either immediate group tCBT treatment or a waitlist control (WLC) group. The results indicated that those receiving the tCBT intervention achieved a significant reduction in their scores on the Beck Anxiety Inventory (BAI; Beck & Steer, 1990), relative to the control group. This improvement was maintained at 6-month follow-up and equivalent to a medium effect size (d=.50). The main shortcomings of this study were its reliance on one self-report questionnaire (BAI; which focuses on physiological aspects of anxiety and so may not be equally sensitive to all anxiety disorders; Cox, Cohen, Direnfeld & Swinson, 1996) and placing no restrictions on receiving concurrent pharmacological or psychological treatment. Interestingly, the authors (Erikson et al., 2007) also criticised the revised protocol claiming that it presented too much information and taught too many skills.

2.7.2 Larkin et al.'s (2003) protocol

Larkin et al. (2003) developed an 8-week, group tCBT protocol aimed at alleviating all the major anxiety disorders apart from OCD and PTSD. Larkin et al. (2003) presented unpublished outcome data from an uncontrolled trial at a national conference (details taken from Norton & Philip, 2008). Twenty-five treatment completers demonstrated significant reductions in both self- and clinician-rated measures of anxiety and overall functioning at post-treatment. However, this was an uncontrolled study with no follow-up, and limited diagnostic applicability, therefore the findings lack generalisability and rigour.

2.7.3 Garcia's (2004) protocol

Garcia (2004) has also developed an 8-week, group tCBT protocol targeting any anxiety disorder. Garcia (2004) published outcome data from an uncontrolled trial where 19 'treatment completers' (who attended over 50% of the sessions) were compared with 25 participants who either attended none (n=4) or less than 50% of the sessions (n=20). Garcia (2004) reported that the treatment completers demonstrated significant reductions in self-reported anxiety and depression at post-treatment compared to the 'non-completers'. Treatment completers were also more likely to be discharged from the service (74% vs. 28%) and have reduced anxiolytic use (44% vs. 11%) at 1-year follow-up, however, no data on self-reported anxiety and depression was collected at this time-point, so it is not known whether symptom reductions were maintained. Furthermore, participant diagnoses were not formally assessed and participants were not required to meet diagnostic criteria for an anxiety disorder to be included in the study, therefore the severity of the sample is unclear and the results lack generalisability.

2.7.4 Schmidt & Woolaway-Bickel (2002) protocol

Schmidt & Woolaway-Bickel (2002) created a 10-week, group tCBT protocol (False Safety Behavior Elimination Therapy; F-SET) exclusively for individuals suffering with GAD, SAD and/or PD. Schmidt et al. (2012) then examined the efficacy of this protocol, randomly allocating 96 participants to either the F-SET or a WLC group. Schmidt et al. (2012) demonstrated that those receiving the tCBT intervention achieved significant reductions on post-treatment measures of anxiety and depression, which were maintained at 6-month follow-up. Furthermore, post-treatment effect sizes fell within the very large range for anxiety measures (d =1.31 to 1.62) and medium range for depression measures (d = 0.70), despite the protocol not including any depression-specific techniques. However, along with the limited diagnostic applicability of this protocol, there were several key methodological limitations to Schmidt et al.'s (2012) study. For instance, medication doses and concurrent CBT were not controlled during the follow-up phase, therefore it is possible that treatment gains may have been maintained by the initiation of new treatments during this period. Furthermore, clinicians completing the follow-up assessments were not blind to the participant's experimental group, and therefore the maintenance of treatment gains could be attributable to assessor bias.

Table 2: Summary of treatment studies examining tCBT protocols for anxiety and/or depressive disorders

Protocol	Study	N	Diagnoses	Design/ Format	Cohen's *d*	Treatment	Components	Main findings	Main criticisms
Erikson (2003)	Erikson (2003)	70	Anxiety (GAD, SAD, PD, AG &/or PTSD)	UCT/ GRP	0.63*	12-weeks, 2-hour sessions	Psycho-education, relaxation, exposure cognitive, behavioural & assertiveness skills, relapse prevention	+ Significant reductions on self-reported measures of anxiety and related avoidance + Gains maintained at 6-month follow-up.	- Uncontrolled study - Unrepresentative sample (76% female) - Limited diagnostic applicability - Concurrent pharmacological treatment allowed (n=96%) - Follow-up data based on 31% of sample (n=22)
	Erikson et al. (2007)	152	Anxiety (except NOS)	RCT/ GRP	0.09	11-weeks, 2-hour sessions vs. WLC group	Revised version of Erikson (2003) with removal of assertiveness skills and more cognitive restructuring	+ Significant reductions on BAI relative to WLC group + Gains maintained at 6-month follow-up.	- Data based exclusively on 1 outcome measure - No limitations on concurrent treatments
Larkin et al. (2003)	*Unpublished presentation*	25	Anxiety (GAD, SAD, &/or PD/AG)	UCT/ GRP	1.14*	8-weeks, 90-minute sessions	Progressive muscle relaxation, deep breathing, guided imagery, cognitive restructuring, exposure & relapse prevention	+ Significant reductions on measures of anxiety and overall functioning at post-treatment.	- Uncontrolled study - No follow-up data - Limited diagnostic applicability - Small sample size
Garcia (2004)	Garcia (2004)	19	Anxiety (not formally assessed)	UCT/ GRP	0.80*	8-weeks, 90-minute sessions vs. non-completers	Psycho-education, relaxation, exposure, cognitive restructuring, thought distraction techniques & relapse prevention	+ Significant reductions in anxiety and depression at post-treatment compared to the 'non-completers'. + Treatment completers more likely to be discharged from the service and have reduced anxiolytic use at	- Uncontrolled study - No follow-up data on self-reported anxiety and depression symptoms - Participants did not need to meet diagnostic criteria for an anxiety disorder for inclusion

								1-year follow-up.	- Small sample size
Schmidt & Woolaway-Bickel (2002) *Unpublished Protocol*	Schmidt et al. (2012)	96	Anxiety (GAD, SAD &/or PD)	RCT/ GRP	1.15	10-weeks, 2-hour sessions vs. WLC group	Psycho-education, identification of safety behaviours, systematic reduction of safety behaviours whilst increasing relevant 'antiphobic' activities	+ Significant reductions in anxiety and depression at post-treatment compared to WLC group. + Gains maintained at 6-month follow-up. + 12-week stabilisation of medication doses required	- Unrepresentative sample (72% female) - Limited diagnostic applicability - Medication stability and concurrent CBT not controlled during follow-up phase - Clinician-assessors not blind to experimental condition at follow-up assessment - Non-active control condition
Norton & Hope (2005)	Norton & Hope (2005)	23	Anxiety (any)	RCT/ GRP	1.61	12-weeks, 2.5-hour sessions vs. WLC group	Psychoeducation, self-monitoring, cognitive restructuring, exposure, relapse prevention	+ 67% of the intervention group saw the severity of their anxiety disorders reduce to subclinical levels, compared to 0% of the WLC group. + Participants with a secondary depression diagnosis (35%) noted a significant decrease in depressive symptoms and overall depression severity compared to WLCs.	- Small sample size - Only a very small proportion of the sample had a secondary depressive disorder and could be included in this analysis (n=8; 35%). - No follow-up data - Non-active control condition
	Norton (2008)	52	Anxiety	UCT/ GRP	1.06*	12-weeks, 2.5-hour sessions	See Norton & Hope (2005)	+ Significant reductions in self-reported anxiety symptoms pre- to post-treatment + No evidence of differential improvement between those with a single or	- Uncontrolled study - No follow-up data - Principal diagnoses mainly limited to SAD (48%) and PD (42%) - Data relied on one outcome measure

								concurrent mood disorder. + Achieved similar effect size (d=1.68) to disorder-specific CBT for anxiety disorders	- Lack of complete pre- to post-treatment assessment data
	Norton (2012)	52	Anxiety	RCT/ GRP	0.20	12-weeks, 2.5 hour sessions of tCBT vs. 12-week relaxation training	See Norton & Hope (2005)	+ Significant but equivalent improvement in anxiety symptoms achieved across the two conditions + tCBT associated with less drop-out (29.7%) than the relaxation intervention (57.1%).	- High rates of attrition - No follow-up data - Principal diagnoses mainly limited to SAD (43%), PD (35%) and GAD (17%)
Titov et al. (2010)	Titov et al. (2010)	86	Anxiety	RCT/ IT	0.78	6 weekly online sessions vs. WLC group	Psychoeducation about anxiety, physical symptoms and cognitive therapy, graded exposure, assertiveness training & relapse prevention.	+ 40% of the treatment group were classified as in remission at post-treatment, compared to just 8% of the WLC group. + Significant reduction in scores on disorder specific measures for GAD, SAD and PD at post-treatment in the treatment group. + However, when compared to the WLC group, only a significant reduction in diagnosis-specific scores found for participants with PD	- Limited therapeutic content - Restricted diagnostic applicability - Non-active control condition
Titov et al. (2011)	Titov et al. (2011)	72	Anxiety (PD, SAD &/or GAD) & Depression	RCT/ IT	0.56	8 weekly online sessions vs. WLC group	Based on Titov et al (2010) plus additional psycho-education on depression, behavioural	+ Significant reductions in self-reported symptoms of anxiety and depression, equivalent to a medium between-group effect size (d=0.55), relative to the	- Insufficient sample size to establish effect of comorbid diagnoses. - No follow-up data for WLC group - Diagnostic assessors not

							activation, and cognitive restructuring.	WLC group. + Comorbid mood disorders reduced considerably from 87% to 31% at 3-month follow-up in the treatment group.	blind to experimental condition.
McEvoy & Nathan (2007)	McEvoy & Nathan (2007)	143	Anxiety & Depression	UCT/ GRP	0.42*	11-weeks, 2-hour sessions	Psychoeducation about anxiety and depression, behavioural activation, exposure, cognitive restructuring, calming techniques, relapse prevention.	+ Significant reductions in self-reported anxiety and depression + Gains maintained at 1-month follow-up + Equivocal effect sizes and reliable change indices achieved when compared to disorder-specific treatment studies treatment studies.	- Uncontrolled study - Treatment adherence not monitored or assessed - Short follow-up period, 35% drop-out at follow-up and no comparison data limit reliability of follow-up data - Medication changes not controlled
Barlow et al. (2011)	Ellard et al., (2010)	15	Anxiety & Depression	UCT/ IND	0.60*	15, 1-hour sessions	Psychoeducation about emotions and behaviour, cognitive reappraisal, reduction of emotional avoidance, modification of emotion-driven behaviours	+ Significant pre-to post-treatment reductions in anxiety and depression symptoms + 56% achieved 'responder status' and 33% HESF at post-treatment	- Uncontrolled study - Small sample size - No follow-up data
	Ellard et al., (2010)	15	Anxiety & Depression	UCT/ IND	0.68*	18, 1-hour sessions	Revised version of Barlow et al., (2011) with some reordering of treatment concepts, increased emphasis on adaptive nature of emotions, plus	+ Significant pre-to post-treatment reductions in anxiety and depression symptoms + Proportion of participants achieving 'responder status' increased from 56-73% and HESF from 33-	- Uncontrolled study - Small sample size

							inclusion of motivation enhancement techniques, in-session mindfulness and mood-induction exercises.	60% + HESF increased further still at 6-month follow-up to 69%	
	Farchione et al., (2012)	37	Anxiety & Depression	RCT/ IND	1.42	18, 1-hour sessions	Revised version of Barlow et al., (2011)	+ Significant reductions in diagnostic severity for both principle and comorbid disorders, self-reported symptoms of anxiety and depression, and clinician-rated measures of functional impairment, relative to WLC. + Significantly more participants achieving HESF (50%), subclinical status for their primary disorder (52%) and treatment responder status (59%) compared to WLCs (0% in all cases) at post-treatment. + Treatment gains further increased at 6-month follow-up	- Small sample size - Treatment fidelity not evaluated - Non-active control condition
	Ehrenreich et al., (2009)	3	Adolescents with Anxiety & Depression	CS/ IND	--	15, 1-hour sessions	Adapted version of Barlow et al., (2011) - language and examples adapted to make more developmentally appropriate, 2	+ Significant reductions in anxiety and depression symptoms at post-treatment + Treatment gains further increased at 6-month follow-up	- Uncontrolled study - Very small sample size - Sample predominantly anxious rather than depressed

							parent sessions	+ High treatment satisfaction	
Ehrenreich-May & Bilek (2012)	Bilek & Ehrenreich-May (2012)	22	Children with Anxiety and Depression	UCT/ GRP	1.07*	15-weeks, 90-minute sessions	Based on Barlow et al's. (2011) UP - emphasis on emotion education and parental involvement. 'CLUES' skills, introduced sequentially: Consider how I feel (sessions 1-4), Look at my thoughts (session 5), Use detective thinking (sessions 6-7), Experience my fears and feelings (sessions 8-14), and Stay healthy and happy (session 15).	+ Significant and clinically meaningful reductions in diagnostic severity and child-reported anxiety and parent-reported depressive symptoms at post-treatment. + 73% of the sample were classified as 'treatment completers' + Majority of parents and children indicated a high degree of satisfaction with the intervention	- Uncontrolled study - Small sample size - Study limited to children with a principal anxiety disorder and only 4 anxiety disorders represented in the sample (GAD, SAD, SP, & Separation Anxiety Disorder)
Barlow et al., (2011)	Ellard et al., (2012)	3	Adults with Bipolar and comorbid anxiety disorders	CS/ IND	--	15, 1-hour sessions	See Ellard et al., (2010)	+ Promising reductions on self- and clinician-rated measures of mania, anxiety, depression and global impairment.	- Uncontrolled study - Very small sample size - No follow-up data

Notes: CS = case series; RCT = randomised controlled trial; UCT = uncontrolled trial; WLC = waiting list control; GRP = group; IT = internet; IND = individual; HESF = high end state functioning; BAI = beck anxiety inventory; GAD = generalised anxiety disorder; SAD = social anxiety disorder; PD = panic disorder; AG = agoraphobia; PTSD = post-traumatic stress disorder; NOS = not otherwise specified; -- = outcome data not currently available; * = UCT whereby the mean standardised difference (MSD) was calculated as the difference between the post- and pre-treatment scores divided by the post-treatment *SD* (the MSD for the RCT studies was calculated using the difference in outcome score between the intervention and control group divided by the pooled *SD)*.

2.7.5 Norton & Hope's (2005) protocol

Amongst all the tCBT protocols for anxiety developed to date, Norton and Hope's (2005) has received the most attention. Norton and Hope (2005) developed a 12-week, group tCBT protocol for a range of anxiety disorders, which consists of 2.5-hour sessions attended by 6 to 8 participants. In an initial trial, the authors randomly allocated 23 participants with a wide range of anxiety disorders to either the 12-week group intervention or a WLC group. Results indicated that when compared to the WLC group, 67% of the intervention group saw the severity of their anxiety disorders reduce to subclinical levels. Moreover, in a subsequent analysis of Norton and Hope's (2005) data, Norton, Hayes and Hope (2004) revealed that whilst the transdiagnostic treatment did not utilise any specific depression techniques, participants with a secondary depression diagnosis (35%) noted a significant decrease in depressive symptoms and overall depression severity compared to WLCs. This finding is consistent with the notion that anxiety and depression have a shared underlying structure (Clark & Watson, 1991), and illustrates the utility of transdiagnostic approaches to comorbid mood disorders. However, this finding requires replication with a larger sample in order to assert this claim more confidently as only a very small proportion of the sample had a secondary depressive disorder and could be included in this analysis (n=8; 35%).

In an open trial Norton (2008) further examined this 12-week group tCBT intervention. The sample comprised 52 participants with an anxiety disorder, 48% of whom had a primary diagnosis of SAD, 42% had a primary diagnosis of PD and 56% had a comorbid anxiety or depressive disorder. Norton's (2008) session-by-session analysis of self-reported anxiety symptoms revealed that participants tended to improve over treatment, and there was no evidence of differential improvement between those with a single or concurrent mood disorder. Furthermore, Norton (2008) achieved a similar effect size

(*d*=1.68) to that reported in a meta-analytic review of disorder-specific CBT for anxiety disorders (Norton & Price, 2007). Although, these initial findings were encouraging, the trial was uncontrolled, did not produce follow-up data and mainly consisted of individuals with SAD or PD. Therefore the causal attribution, persistence and generalisability of the results could not be established.

Norton (2012) further scrutinised this protocol by comparing it to another psychological intervention; a 12-week relaxation training program. Eighty-seven participants with any anxiety disorder were randomly allocated to either condition. The comparison revealed significant but equivalent improvement in anxiety symptoms across the two conditions. However, the relaxation training intervention was associated with a higher dropout rate (57.1%), which suggests that it may have been relatively less acceptable to participants than the tCBT intervention (29.7%). The causes of these high rates of attrition are unclear, although participants do not appear to have withdrawn due to symptom relief, as self-reported anxiety symptoms remained elevated (Norton, 2012). Again, this study did not collect follow-up data and consisted of participants from a narrow range of anxiety disorders (SAD, PD & GAD), therefore the persistence and generalisability of the results could not be established. Furthermore, there was no placebo-control condition meaning that the relative specific and non-specific contributions of these interventions could not be examined.

2.7.6 Titov et al.'s (2010) Anxiety Program protocol

Titov et al. (2010) created the Anxiety Program; the first tCBT internet protocol for individuals with PD, SAD and/or GAD. Each session is designed to be completed weekly and is accompanied by a summary and related homework assignment. In a RCT Titov et al. (2010) randomly allocated 86 participants to either a treatment or WLC group. Intention-to-treat analyses revealed that 40% of the treatment group were classified as in remission, compared to just 8% of the

control group at post-treatment. Overall the treatment group also demonstrated a significant reduction in scores on disorder specific measures for GAD (Generalized Anxiety Disorder – 7 item; GAD-7), SAD (Social Phobia Screening Questionnaire; SPSQ), and PD (Panic Disorder Severity Scale – Self Report Scale; PDSS-SR) at post-treatment. However, when compared to the control group, there was only a significant difference found for participants with PD on the PDSS-SR, which suggests that the Anxiety Program is not as effective at relieving anxiety symptoms relative to existing disorder-specific internet programs for these disorders (Titov et al., 2009; Titov, Andrews & Schwencke, 2008).

2.7.7. Summary of tCBT protocols for anxiety disorders

In summary, each of the tCBT protocols reviewed above appear to deliver promising results for individuals with anxiety disorders and studies evaluating these protocols suggest that tCBT is associated with symptom relief and achieve better outcomes than WLCs. Furthermore, whilst more research is required, some evidence suggests that tCBT can achieve similar outcomes for individuals with comorbid anxiety disorders and equivocal effect sizes to anxiety disorder-specific CBT protocols (Norton, 2008). However, although these findings are encouraging, most of these protocols were evaluated with uncontrolled research designs (Erikson, 2003; Larkin et al., 2003; Garcia, 2004; Norton, 2008; so it cannot be ruled out that factors other than the intervention contributed to symptom improvement), and did not collect reliable follow-up data (Erikson, 2003; Larkin et al., 2003; Garcia, 2004; Norton & Hope, 2005; Norton, 2008; Norton, 2012) so the persistence of treatment gains over time is unknown. Moreover, their utility to older people with emotional disorders is greatly restricted as all of these protocols are designed to be delivered in a group format (or over the Internet; Titov et al., 2010), which can present barriers and (Barrowclough et al., 2001) and poorer outcomes (Engles & Verney, 1997) for older people. They are also only applicable to (or been evaluated with) a narrow

subset of anxiety disorders (Erikson, 2003; Larkin et al., 2003; Schmidt & Woolaway-Bickel, 2002; Norton & Hope, 2005) therefore offer little utility to a population where anxiety and depression tend to co-occur (Beekman et al., 2000).

2.8 tCBT protocols for anxiety and depressive disorders

2.8.1 Titov et al.'s (2011) Wellbeing Program protocol

Titov et al. (2011) later developed and extended the Anxiety Program to create the Wellbeing Program; an 8-session internet program for individuals with depression and/or anxiety (PD, SAD, and GAD). Titov et al. (2011) recruited 72 participants to examine the efficacy of the Wellbeing Program in a RCT and demonstrated that relative to a WLC group, those allocated to the treatment group achieved significant reductions in self-reported symptoms of anxiety and depression, equivalent to a medium between-group effect size (d=0.55). Furthermore, the number of participants in the treatment group with comorbid mood disorders reduced considerably from 87 to 31% at 3-month follow-up. However, although the sample size was sufficient to detect between-group differences, it was insufficient to establish the effect of comorbid diagnoses (Titov et al., 2011). Other limitations were that the diagnostic assessors were not blind to the experimental condition and participants in the control group were not assessed at follow-up, both of which could have biased the results.

2.8.2 McEvoy & Nathan's (2007) protocol

McEvoy & Nathan (2007) created an 11-week, group tCBT protocol for people with anxiety and depression. McEvoy & Nathan (2007) recruited 143 participants (21% with an anxiety disorder, 27% with a depressive disorder and 52% with a comorbid anxiety and depressive disorder) to examine the efficacy of their protocol. The results revealed significant reductions in self-reported anxiety and depression, which were maintained at 1-month follow-up and

equivocal effect sizes and reliable change indices when compared to methodologically similar disorder-specific treatment studies. However, the short duration of and drop-out (35%), which occurred during the follow-up period, plus the lack of comparison data limit the reliability and validity of the follow-up data. Furthermore, adherence to the treatment protocol was not assessed, which threatens the internal validity of the study.

2.8.3 Summary of tCBT protocols for anxiety and depressive disorders

There are far fewer tCBT protocols available that are applicable to both anxiety and depressive disorders, and only one of these is designed to be delivered face-to-face (McEvoy & Nathan, 2007), although this in a group format, which is a less feasible and effective format to be delivered with older people (see section 2.7.7). Furthermore, although McEvoy & Nathan's (2007) protocol achieved promising outcomes on self-reported anxiety and depression symptoms, the only study to examine its efficacy lacked methodological rigour on several fronts (uncontrolled, treatment adherence not assessed, unreliable follow-up data) and therefore further research is required before the efficacy of this protocol can be established and successfully adapted to other audiences.

2.9 Barlow et al.'s (2011) Unified Protocol (UP)

Barlow et al. (2011) have developed an individualised tCBT protocol designed to be applicable to both anxiety and depressive disorders. The UP distils traditional, empirically supported CBT techniques and incorporates these with principles of emotional regulation and dysregulation (Wilamowska et al., 2010). The UP comprises 4 main treatment components: (1) psychoeducation about emotions and behaviour; (2) changing misappraisals about probabilities and consequences of negative experiences; (3) preventing avoidance of negative emotion triggers; and (4) modifying emotion-driven

behaviours (e.g. hypervigilance, withdrawal). For a more in depth description of the protocol refer to section 3.6.

2.9.1 Advantages of using the UP

In Clark's (2009) discussion of tCBT he delineates the UP from the other tCBT protocols outlined above and states that it offers the most coherent and theory driven protocol for the treatment of emotional disorders. Clark (2009) argues that most other tCBT protocols (e.g. Norton & Hope, 2005, Erickson et al., 2003) assume an atheoretical and practical approach; combining CBT strategies from disorder-specific protocols, whilst not attempting to target the shared psychological processes or underlying vulnerabilities to emotional disorders. Other benefits to using the UP include that it is explicitly designed to alleviate both anxiety and depressive disorders (as opposed to a subset of anxiety disorders), and therefore is likely to be more appropriate for adaptation to an older audience in which these disorders are highly comorbid. The UP is also delivered in an individual (as opposed to a group) format, which is often preferable for older people, where mobility, financial and caring concerns can restrict access to groups. In contrast, individually delivered treatments can be provided more flexibly and within the person's home. The emerging research examining the efficacy of the UP with working-age people is also strong, as detailed in the next section.

2.9.2 Research examining the efficacy of the UP

Ellard et al. (2010) presented data from 2 open, clinical trials. An open (as opposed to a randomised-controlled) trial does not include a control-group comparison, thereby fails to control for the validity threats of spontaneous remission. Therefore, the extent to which the UP reduced symptoms beyond no intervention here is unknown. The first trial examined an initial version of the UP with 15 participants with heterogeneous anxiety and depressive disorders. Participants had an average of 1.94 diagnoses at pre-treatment (*SD*=0.64, range 1

to 3) including GAD (n=7), SAD (n=8), OCD (n=5), PD (n=4), PTSD (n=1), HA (n=2), SP (n=1), major depression (n=5) and dsythmia (n=2). Results from the first trial demonstrated significant pre- to post-treatment improvements in anxiety and depression symptoms. At post-treatment, 56% of participants achieved responder status (defined by a 30% or more decrease on at least 2 outcome measures) and 33% high end-state functioning (HESF) on principle diagnoses (defined by no longer meeting criteria for their principle diagnosis and scoring within the non-clinical range on at least 1 outcome measure). In terms of post-treatment effects on comorbid diagnoses, 71% of participants achieved responder status and 50% HESF. These initial findings were promising, albeit modest and would have benefited from the additional collection of follow-up data A series of protocol modifications followed including some reordering treatment concepts, increased emphasis on the adaptive nature of emotions (session1), the inclusion of motivation enhancement techniques, and in-session mindfulness and mood-induction exercises.

In a second trial Ellard et al. (2010) examined this revised version of the UP with a demographically comparable sample of 15 participants again with heterogeneous anxiety and depressive disorders including GAD (n=6), SAD (n=8), OCD (n=5), PD (n=4), HA (n=1), SP (n=2), anxiety disorder NOS (n=1), major depression (n=2) and dsythmia (n=1). Results from the second trial again demonstrated significant pre- to post-treatment improvements in anxiety and depression symptoms The percentage of participants achieving responder status and HESF at post-treatment rose from 56 to 73%, and 33 to 60% respectively. At 6-month follow-up the percentage of responders (85%) and those classified with HESF (69%) increased further still. In terms of comorbid diagnoses, there was a slight decrease in the percentage of participants achieving responder status at post-treatment (from 71 to 64%), but this was surpassed at 6-month follow-up (80%). There was also an increase in participants with comorbid diagnoses achieving HESF at post-treatment (from 50 to 64%), however this returned to 50% at 6-month follow-up. Despite the methodological

shortcomings of these uncontrolled and underpowered studies, the adaptations made to the UP appear to have enabled substantially greater outcomes for individuals with anxiety and depression.

Most recently, Farchione et al. (2012) evaluated the effectiveness of Ellard et al.'s (2010) revised version of the UP in an RCT. Thirty-seven people with a principle anxiety disorder were randomly assigned to receive individual tCBT either immediately or following a 16-week delay. The average number of diagnoses at pre-treatment was 2.16 (*SD*=1.19, range 1 to 5) and about a third of the sample (32%) had a comorbid depressive disorder (18% of the tCBT condition and 14% of the WLC condition). In comparison to those in the delayed treatment condition, those receiving tCBT achieved significant reductions in diagnostic severity for both principle and comorbid disorders, self-reported symptoms of anxiety and depression, and clinician-rated measures of functional impairment. Furthermore, the tCBT condition resulted in significantly more participants achieving HESF (50%), subclinical status for their primary disorder (52%) and treatment responder status (59%) compared to the WLC group (0% in all 3 cases) at post-treatment. These gains increased at 6-month follow-up from 50 to 64% for HESF, 52 to 71% for subclinical status and 59 to 71% for responder status. Importantly, there were no significant differences between the proportion of participants with different principle diagnoses achieving HESF, subclinical or responder status, which suggests that the UP is equally effective across the emotional disorders, although a larger sample size would be needed to confirm this. Farchione et al. (2012) also reported that the 67% of those participants with a comorbid depressive disorder achieved HESF, subclinical and responder status at post-treatment, rising to 89% at 6-month follow-up. However, treatment fidelity was not examined here so it is not certain that each therapist consistently delivered the UP with each participant.

Altogether these robust findings suggest that the UP can achieve an efficacious impact on comorbid emotional disorders, however,

replication with a larger sample is required. To this end the Barlow group is currently conducting a large, non-inferiority clinical trial directly comparing the UP to disorder-specific CBT protocols. The results of this trial will help to establish whether the UP is equally efficacious to the established disorder-specific protocols for the treatment of anxiety and depressive disorders.

2.9.3 Adaptations and applications of the UP to other populations

The UP is also gathering promising evidence in terms of its feasibility, acceptability and preliminary outcomes when adapted and applied to other populations, including children, adolescents and adults with Bipolar depression. Ehrenreich et al. (2009) first modified and applied the UP to three adolescents (aged 12-16 years) with anxiety and depressive symptoms. These initial modifications were purposefully minimal in order to be faithful to the UP's theoretical focus and to systematically identify areas requiring more extensive modification. Ehrenreich et al.'s (2009) initial modifications centred around making the language and examples more developmentally appropriate, and facilitating parents' participation in and understanding of the treatment through 2 additional parent sessions. The application of this revised protocol yielded a reduction in anxiety and depression symptoms at post-treatment, and most notably at 6-month follow-up. Following this preliminary investigation Ehrenreich and Barlow (2007) further modified the UP for the treatment of emotional disorders in Youth (UP-Y) ahead of a planned open trial.

Ehrenreich-May and Bilek (2012) examined the utility of extending the UP to younger children (aged 7-12 years) with emergent anxiety and depressive symptoms through the creation of the Emotion Detectives Treatment Protocol (EDTP); a 15-session tCBT group program. Whilst this protocol retains the core principles of the UP it differs considerably in terms of its structure and approach, and places a greater emphasis on emotion education and parental involvement. Bilek and Ehrenreich-May (2012) examined the

feasibility, acceptability and preliminary post-treatment outcomes of the EDTP in an open trial with 22 children with a principal anxiety disorder and secondary depressive symptoms. The authors utilised child and parent versions of self-report questionnaires for anxiety and depression and a post-treatment questionnaire to capture changes in symptomology and treatment satisfaction. In terms of efficacy, intention-to-treat analyses revealed significant and clinically meaningful reductions in overall diagnostic severity and child-reported anxiety and parent-reported depressive symptoms from pre- to post-treatment. Pre to post-treatment reductions in child-reported depression and parent-reported anxiety symptoms were also achieved however these were not statistically significant. In terms of acceptability, 73% of the sample were classified as treatment completers (defined as attending 11 or more sessions) and the majority of parents and children indicated a high degree of satisfaction with the intervention on the post-treatment questionnaire. Overall these findings suggest that it is feasible to usefully adapt the UP to children and adolescents and achieve promising and meaningful changes to anxiety and depression symptoms.

Finally, in a preliminary clinical replication series Ellard et al. (2012) examined the efficacy of applying the UP (without modification) to 3 adults with Bipolar and comorbid anxiety disorders. The outcomes suggested that this application was both feasible and acceptable and led to promising reductions on self- and clinician-rated measures of mania, anxiety, depression and global impairment. Further research using randomised controlled designs are needed though before the short- and long-term efficacy of this application can be established.

2.9.4 Summary

The UP has not yet been adapted and applied to an older audience, however it possesses several advantages over both traditional disorder-specific CBT protocols and other tCBT protocols that are

particularly relevant to older people (individual format, tackles comorbid emotional disorders). Research evidence examining the efficacy of the UP with working-age people is promising and achieved good outcomes in terms of comorbid diagnoses and HESF. Furthermore, preliminary attempts to adapt the UP to a younger audience (Ehrenreich et al., 2009; Bilek & Ehrenreich-May, 2012) and adults with anxiety and Bipolar disorder (Ellard et al., 2012) have proved useful and encouraging in terms of ratings of efficacy, acceptability and feasibility. These together suggest that the UP also has the potential to be successfully adapted and applied to an older audience. The next section outlines examples of the practical and conceptual issues it may be important to consider when adapting and applying the UP to an older audience.

2.10 Adaptations for older people

The older adult population is believed to represent the least homogenous cohort of all the age groups (Laidlaw, 2001), containing at least two generations (Zeiss & Steffen, 1996) and some argue more disparities than similarities (Dick & Gallagher-Thompson, 1995). Therefore, reaching a consensus on whether and how to adapt CBT-type interventions for older people is not straightforward. Whilst some older people may require minimal adaptation, others will require considerably more and what may be required for some, could be inappropriate for others. Despite this challenge, various practical and conceptual modifications have been suggested, which are helpful to consider in applying CBT to older people. These are described in turn below.

2.10.1 Practical adaptations

Setting

CBT is traditionally delivered in out-patient settings, however, the higher incidence of physical health and mobility issues can restrict older people's ability to travel. Barrowclough et al. (2001) argue that where possible older people's access to psychological therapies should be facilitated by services offering flexibility and the possibility of seeing people in their own homes.

Format

There are divergent views as to whether older people benefit most from CBT delivered in a group or an individual format. On the one hand Wetherell, Gatz and Craske (2003) argue that group formats provide additional benefits to older people who may be socially isolated. However, others have questioned whether this stance represents a stereotypical assumption of older people (Charlesworth & Greenfield, 2004). Furthermore, in a meta-analysis of CBT trials for late-life depression Engles and Verney (1997) reported that older people achieved better outcomes when they received CBT individually rather than in a group.

Cognitive changes

Cognitive functioning changes with age and can occur due to medication side effects, however, these changes develop at variable rates and are not universal. Overall, there appears to be a general, but significant decline in working memory, selective attention (Evans, 2007) and 'Fluid intelligence' (G*f*; our ability to attain and analyse new information), coupled with an increase in 'Crystalised intelligence' (G*c*; our ability to employ accrued knowledge skills and experience; O'Brien, 1999). As a general rule of thumb Evans (2007) suggests that where cognitive changes are evident it can be helpful to present new information in different formats (e.g. written, visual etc), encourage note-taking and provide regular summaries of themes and content.

Sensory Impairments

The incidence of sensory impairment also increases with age, the most common being a decline in hearing and sight. It is important to tackle any sensory issues that may impede an older person's ability to engage in sessions and homework assignments. This may involve exploring and challenging any perceived discomfort or negative beliefs associated with using hearing or visual aids (Van den Brink, Wit, Kempen & Heuvelen, 1996). Where the use of aids are insufficient, large print handouts and tape recordings can be used to facilitate engagement.

Homework

Homework assignments represent an important element within CBT protocols due to research evidence that suggests a robust correlation between client's homework compliance and subsequent treatment outcomes (e.g. Burns & Spangler, 2000), and enhanced treatment outcomes for CBT utilising homework assignments (effect size r = .36) compared to CBT consisting of purely 'in-session' work (Kazantzis, Deane & Ronan, 2000). Kazantzis, Pachana & Secker (2003) describe guidelines to enhance homework compliance among older people. In particular the authors emphasise providing older people with a clear rationale for the purpose and benefits of completing each assignment and specific instructions of when, where, how often and for how long an activity should be performed to achieve a successful outcome. Where appropriate homework compliance can also be enhanced with the involvement of family members or carers in the planning and implementation of homework tasks (Teri, Logsdon, Wagner & Uomoto, 1994).

2.10.2 Conceptual adaptations

Laidlaw, Thompson and Gallagher-Thompson (2004) argue that traditional CBT models do not accommodate the specific age-related issues relevant to older people and the presentation of their

psychological difficulties. Laidlaw et al. (2004) therefore propose a series conceptual adaptations it may be important to consider when working with older people. These are discussed in turn below.

Physical Health

The prevalence of physical illness and disability increases as we age (WHO, 2003). Although many older people adjust and manage these difficulties well, for others, poor physical health can significantly impair their ability to engage with, understand and recall therapeutic content (Evans, 2007). Therefore, flexibility with regard to the length of sessions may be needed in order to accommodate symptoms of physical illness such as pain and fatigue. Physical ill health can also limit the application of certain therapeutic techniques such as behavioural experiments. For example, it may be necessary to avoid certain anxiety symptom provocation experiments (such as breathing through a thin straw, or running on the spot) if there are cardiovascular issues or Chronic Obstructive Pulmonary Disease (COPD). Therefore when working with older people, it is particularly important to establish the presence and impact of any health difficulties, examine any related dysfunctional beliefs and negotiate achievable treatment goals (Zeiss, Lewinsohn, Rohde & Seeley, 1996).

Cohort Beliefs

Cohort beliefs relate to the experiences and ideas typically shared by people born within a similar time period. It is important to understand and acknowledge these beliefs as they can impact on the process and outcome of therapeutic interventions with older people (Laidlaw et al., 2004). For instance, the current older generation may share certain beliefs about the cause of psychological distress, tend to view the role of a 'patient' as a submissive recipient of treatment and lack confidence in their capacity to make significant changes in later life. Therefore older people may require a greater degree of socialisation to therapy, and the therapist may need to take a more directive approach and place a greater emphasis on building motivation to encourage behaviour change.

Role Investments

Older people are often faced with the challenge of adapting to various losses (e.g. bereavement, loss of social networks, loss of health) and transitions (e.g. retirement, living arrangements, intergenerational relationships), which can impact negatively on their ability to remain engaged in meaningful and purposeful activities. Difficulties maintaining these role investments are common among older people and can trigger and maintain emotional difficulties (Thompson, 1996), therefore it is important to consider what meaningful activities they have stopped doing and encourage them to gradually restore these.

Intergenerational Relationships

The transition into old age can trigger changes within intergenerational relationships (e.g. parent-child, parent-grandchild). These changes can in turn lead to tensions and disagreements within these relationships and precipitate and maintain emotional difficulties in older people. It is therefore important to consider the influence of intergenerational relationships in the formulation of older people's psychological difficulties.

Socio-cultural context

This refers to the older person's attitude towards their own aging, and can include internalised, negative socio-cultural stereotypes, such as older people are 'useless' or 'too old to change'. It is important that negative beliefs about aging are addressed as they have the potential to exacerbate feelings of helplessness and low self-esteem (Laidlaw et al., 2004) and lead older people to adopt and maintain unhelpful behaviour patterns in line with these beliefs (Evans, 2007).

2.10.3 The UP approach to formulation and how this might incorporate older adult issues.

The initial sessions of the UP treatment manual (sessions 2 and 3) focus on identifying the idiosyncratic qualities of the patients emotional experience using the 'Three-component model of emotional experiences', as well as the triggers to these experiences and the short- and long-term consequences of their reactions. This process enables a bespoke formulation of the patient's mood difficulties to be created as well as a clear rationale and guide for treatment. The simplicity of this formulation is ideal for using with older people. Charlesworth & Reichelt (2004) argue that older people can struggle to engage with complex CBT conceptualisations and therefore recommend using simple 'mini formulations' where possible. An example of how the 'Three-component model of emotional experience' may be applied with an older person and incorporate the conceptual adaptations outlined by Laidlaw et al., (2004) is depicted in Figure 3.

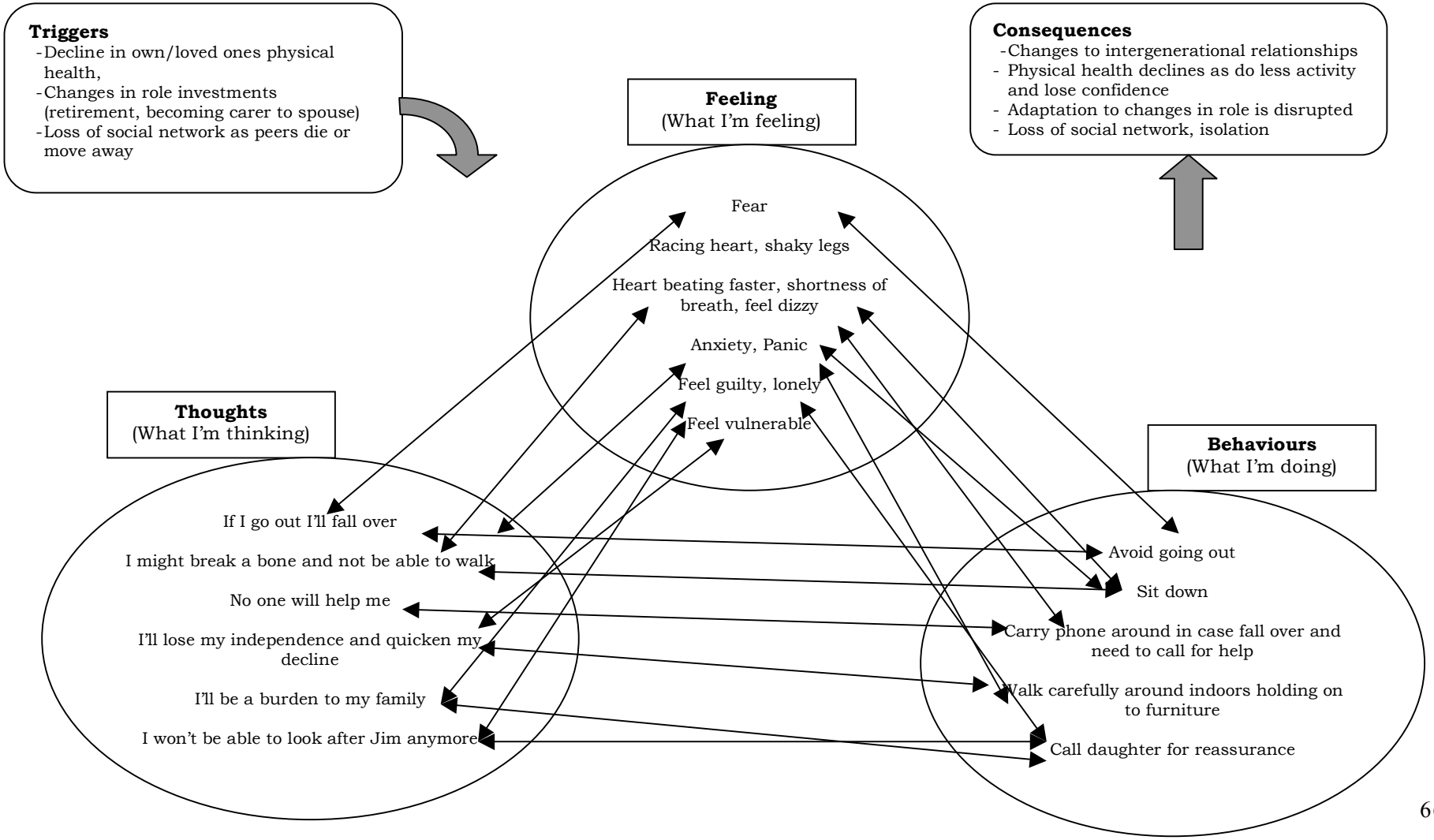
For instance, a decline in physical health may represent a 'trigger' to emotional difficulties and a failure to adapt to changes in physical health by lead to reductions in confidence and physical activity, which further exacerbate physical decline ('consequence'). A deterioration in physical health may also mimic and exacerbate somatic sensations associated with anxiety (e.g. shortness of breath, heart palpitations) further reinforcing perceptions of danger and vulnerability.

Changes in intergenerational relationships (e.g. parent-child) may 'trigger' or exacerbate ('consequence') emotional difficulties. For instance, in the example given in Figure 3, the daughter may begin to perceive her parent as vulnerable/frail, encourage them not to go out alone in case they fall, provide reassurance/care, which undermines their perceived ability to cope, and reinforces a sense of burden, guilt and fear.

Changes in role investments (e.g. becoming a carer to your spouse) may lead to increased isolation, a loss of social network, an increased sense of responsibility and activate certain cohort beliefs (e.g. relating to stoicism and duty). These in turn may give rise to emotional difficulties, which are responded to in a way that prevent adjustment and intensify feelings of guilt or isolation.

The social-cultural context (e.g. negative beliefs about aging) and cohort beliefs may influence the content of maladaptive thoughts, and perceptions of vulnerability and ability to cope.

Figure 3: The 'Three-component model of emotional experience' (UP)



2.11 Summary

In summary, tCBT may present a more clinically-effective solution to alleviating comorbid emotional disorders than traditional disorder-specific methods. It is also likely to enable much needed improvements in the dissemination of and access to evidence-based psychological therapies for older people. Recent trials examining various transdiagnostic CBT protocols for anxiety disorders have revealed beneficial effects of tCBT on anxiety and secondary depression when applied to working-age people. However, the potential benefits and efficacy of this approach have not yet been examined in older people. It is important not to presume its efficacy in older people as their response to tCBT may differ to that of working-age people for numerous reasons (e.g. due to more diverse aetiology and physical comorbidities in older people).

Thus, this study sought to ascertain preliminary estimates of the efficacy of tCBT for comorbid depression and anxiety in comparison to a delayed-treatment control condition in older people. It also aimed to evaluate the feasibility and acceptability of the intervention in this population. This required adapting Barlow et al.'s (2011) UP to both an older audience (e.g. including more age-appropriate vignettes; as the UP was developed for working-age people) and for a UK audience (e.g. removing American spellings and terminology; as the UP was developed in the United States). Preliminary attempts to adapt the UP to a younger audience (Ehrenreich et al., 2009; Bilek and Ehrenreich-May, 2012) and adults with anxiety and Bipolar disorder (Ellard et al., 2012) have proved useful and encouraging, which is promising for the aims of this study.

2.12 Research aims, questions and hypotheses

2.12.1 Aims

This study aimed to evaluate the efficacy, feasibility and acceptability of tCBT versus 7-week delayed-treatment for symptoms of depression and anxiety in older people.

2.12.2 Research questions

i. Do preliminary data suggest that tCBT is efficacious in reducing symptoms of depression and anxiety in older people?
ii. Is it feasible to deliver a tCBT intervention with older, British people with symptoms of depression and anxiety?
iii. Is tCBT acceptable to older people with symptoms of depression and anxiety?

2.12.3 Main hypotheses

i. Preliminary data will suggest that the tCBT intervention can significantly reduce depression and anxiety symptoms among older people relative to a delayed-treatment control condition.
ii. Preliminary data will suggest that tCBT is efficacious in reducing symptoms of anxiety and depression at post-treatment compared to pre-treatment.
iii. It will be feasible to deliver a tCBT intervention with older, British people with comorbid symptoms of depression and anxiety.
iv. The tCBT intervention will be acceptable to older people with comorbid symptoms of depression and anxiety.

3. Method

This study is reported in accordance with the CONSORT statement for clinical trials (Schulz, Altman & Moher, 2010). The clinicaltrials.gov registration ID is NCT01744548. The protocol and supporting CONSORT checklist for this study are available as supporting information (see appendix 1 and 2). Ethical approval was granted by the NHS Health Research Authority - Bromley National Research Ethics Service (NRES) Committee (Approval number: 12/L0/1462; see appendix 3 for the ethical approval letter). All participants provided written informed consent before taking part in the study (see appendix 4 and 5 for the consent form and information sheet). Participants were also invited to give written consent for their tCBT sessions to be audio recorded for the purpose of monitoring treatment adherence (see appendix 6 for the audio consent form).

3.1 Design

The design comprised a pilot randomised, controlled partial-crossover trial with 2 treatment arms. Participants were randomly allocated to receive immediate-treatment plus treatment-as-usual (TAU) or 7-week delayed-treatment plus TAU. The latter arm served as a control condition in order to enable between-group comparisons. The study utilised a 2 (group) x 4 (time) mixed design. Intervention group was a between-subjects factor (immediate-treatment plus TAU vs. delayed-treatment plus TAU) and time was a within-subjects factor (pre- [pre1 for the immediate group, or pre2 for the delayed group] vs. mid- vs. post-treatment). The dependent measures were the scores on the self-rated outcome measures, attrition and treatment completion rates, and satisfaction ratings (see section 3.5.2).

3.2 Randomisation

Participants were randomly allocated to receive individual immediate-treatment plus TAU or 7-week delayed-treatment plus TAU at the point of recruitment. Randomisation with minimisation is the recommended procedure for small samples (Altman & Bland, 2005) and was used to ensure balance in participant characteristics across the treatment groups. MINIM, an MS-DOS software program, was employed to randomly allocate participants using the method of minimisation (Evans, Day & Royston, 1990). Allocation was balanced according to the following variables: sex (male or female), age (<80 years or >80 years), and history of anxiety or depression (yes or no). Equal weighting of importance was given to each variable. The first 2 participants (9% of the target sample size) were randomly allocated according to a coin toss in order to introduce a random element into the procedure. A 1:1 allocation ratio was specified thereafter. Randomisation was completed by a blind, independent researcher, who informed the research supervisor as to allocation status, who then informed the relevant therapist. It was not possible to blind participants and personnel to allocation status due to the study design.

3.3 Participants

Sixteen participants were recruited from CMHTs within the Mental Health for Older Adults and Dementia Clinical Academic Group (MHOA&D CAG), in the South London and Maudsley NHS Trust. The initial screening assessment and tCBT intervention were delivered either within an outpatient clinic, or in participants' homes (depending on each participant's level of mobility).

3.3.1 Inclusion criteria

To be eligible participants needed to (i) meet criteria for a primary diagnosis of depression or anxiety, together with clinical symptoms of another mood disorder (e.g. anxiety or depression respectively), or a mixed anxiety and depressive disorder (as outlined in ICD-10; WHO, 1992), as assessed by the Structured Clinical Interview for DSM Disorders (SCID; First, Williams, Spitzer & Gibbon, 2007). Participants also needed to (ii) be aged 60 years and above; (iii) be fluent in English and have sufficient literacy skills to cope with the demands of the intervention (e.g. reading handouts, completing questionnaires); (iv) and score 8 (clinical cut-off) or above on the Hamilton Anxiety Rating Scale (HAM-A; Hamilton, 1959) or Hamilton Depression Rating Scale (HAM-D; Hamilton, 1960) for their primary diagnosis.

3.3.2 Exclusion criteria

Exclusion criteria included: (i) a current diagnosis of PTSD or complicated grief (as there is evidence that these disorders may not be amenable to transdiagnostic treatments; Erickson, Janeck & Tallman, 2009); (ii) a severe and enduring mental health disorder (e.g. schizophrenia, schizoaffective disorder, bipolar disorder); (iii) presence of a personality disorder; (iv) presence of an intellectual disability or cognitive impairment (e.g. scoring less than 26 on the Mini-Mental State Examination [MMSE]; Folstein, Folstein, & McHugh, 1975); (v) severe sensory impairment that would significantly impair a person's ability to engage in the intervention; (vi) neurodegenerative disease (e.g. dementia) or a neurological condition (e.g. stroke, Parkinson's disease, head injury); (vii) current alcohol/substance abuse or dependence; (viii) current suicidal risk with intent; (ix) receiving concurrent psychotherapy; and (x) if the care coordinator deemed that the potential participant should a) receive urgent psychological therapy or b) would not be able to wait 7-weeks for therapy (should they be allocated to the delayed-treatment condition).

3.3.3 Changes made to eligibility criteria

Two changes to the eligibility criteria were made after the commencement of this study in order to facilitate recruitment rates. Firstly, participants were originally required to score between 8 (clinical cut-off) and 30 (upper limit of 'severe' range) on the HAM-A or between 8 (clinical cut-off) and 22 (upper limit of 'severe' range) on the HAM-D for their primary diagnosis. However, the criterion to score below the upper limit ('very severe' range) was later removed as potential participants were frequently scoring above these cut-offs, and therefore this requirement was limiting the study's recruitment rates. With the removal of this criteria, an additional safeguard was put in place; potential participants' care co-ordinators were contacted and asked to consider whether the potential participant 1) required urgent psychological therapy; or 2) would not be able to wait 7 weeks for therapy (should they be allocated to the delayed treatment condition). If either of these were true then the participant was excluded from participating in the study. Secondly, participants were originally required to stabilise on their psychotropic medication (if prescribed) for a minimum of 8-weeks before commencing in the study. However, this requirement was later removed as psychotropic medication was frequently being changed at the point of referral to the CMHT, which precluded potential participants from participating in the study due to the impact this would have on their wait for therapy (up to a maximum of 15 weeks if allocated to delayed-treatment rather than 7 weeks).

3.4 Power calculation

The original aim was to recruit 22 older people with depression and anxiety (11 per treatment condition). Due to slow recruitment rates 16 older people were recruited, which was sufficient to provide estimates of feasibility and acceptability of tCBT. In order to estimate the sample size required to gain preliminary estimates of the efficacy

of tCBT, an *a priori* power analysis was conducted using Hedge's G effect sizes reported in Farchione et al's (2012) recent evaluation of the UP with working-age people. Farchione et al (2012) reported effect sizes of 1.11 for one depression outcome measure and 1.10 for an anxiety outcome measure (based on between-group differences in post-treatment scores). Therefore, based on the between-group effect sizes of 1.11 and 1.10, a sample size of 22 was sufficient to yield statistical power of 80% at an alpha level of 0.05. Thus, the proposed sample size was sufficient to provide preliminary estimates of the efficacy of tCBT in comparison to 7-week delayed treatment. Based on advice from MHOA&D CAG therapists, it was anticipated that attrition rates would be low due to flexibility of the intervention's location of delivery. With an estimated attrition rate of 18% (4 participants in total), a sample size of 18 would still be sufficient to yield statistical power of 72% (for between-group analyses) and >95% (for within-group analyses) at an alpha level of 0.05.

3.5 Assessment measures and intervals

3.5.1 Screening measures

An initial screening assessment was conducted with each participant in order to determine whether they met the study inclusion criteria and to determine mental health diagnoses. The screening assessment utilised the SCID to establish mental health diagnoses, the MMSE to screen for cognitive impairment, a semi-structured interview to assess demographic and clinical characteristics, clinician-rated mood measures to determine disorder severity (HAM-A and HAM-D) and two self-rated mood measures: the CORE-10 (Connell & Barkham, 2007) and the HADS (Zigmond & Snaith, 1983). The SCID was selected to establish mental health diagnoses as it is has been found to yield highly reliable diagnoses across the axis I disorders (e.g. Ventura et al., 1998; Kranzler et al., 1996; Skre, Onstad, Torgerson & Kringlen, 1991; Sanchez-Villegas et al., 2008). Each screening assessment was completed by one the study therapists (whom had substantial

experience utilising the screening measures selected), and took between 1.5 to 2.5 hours to complete.

3.5.2 Primary outcome measure and assessment intervals

The primary outcome measure was the HADS, which was used to evaluate the effectiveness of the tCBT intervention. The HADS was completed on a weekly basis throughout the intervention period. Once participants in the delayed-treatment arm crossed over into the treatment arm they were evaluated as per the immediate-treatment group. Table 2 illustrates the assessment intervals and what time points they corresponded to for the immediate and delayed-treatment groups.

Table 3: Assessment intervals and corresponding time points for the immediate- and delayed-treatment groups.

Group	**Pre1**	**Pre2**	**Mid**	**Post**
Immediate	√	-	√	√
Delayed	√	√	√	√

√ *Assessment collected*

- Assessment not applicable

3.5.3 Secondary outcome measures

The secondary outcome measure selected to evaluate effectiveness was the CORE-10, which was completed at pre- (1&2), mid- and post-treatment (see Table 3).

The feasibility of the tCBT intervention was assessed based on attrition rates due to practical reasons (e.g. difficulty in attending due to mobility issues or physical health problems, etc) and clinician-rated judgments of the intervention (see appendix 7). A Discharge Satisfaction Questionnaire (developed for the Psychology and Psychological Therapies Service within the MHOA&D CAG), completed

at post-intervention was used to evaluate the acceptability of the tCBT intervention. This questionnaire assesses satisfaction with therapy using both quantitative and qualitative items (see appendix 8). Acceptability was also evaluated in terms of attrition rates due to dissatisfaction with the intervention and homework compliance.

3.6 Description of the tCBT intervention

The tCBT intervention comprised 12 individual, 1-hour sessions based upon an adapted version of Barlow et al's (2011) UP. Permission to adapt the UP was granted by the Barlow group. A 12 session format was chosen to reflect the routine, local psychology provision, which offers patients between 8 to 12 CBT sessions. Furthermore, Boisseau et al. (2010; Barlow group) state "treatment is typically conducted over the course of 12 to 18 sessions, with each session lasting approximately 50 to 60 minutes" (p102). The UP comprises 4 main treatment components: (1) psychoeducation about emotions and behaviour; (2) changing misappraisals about probabilities and consequences of negative experiences; (3) preventing avoidance of negative emotion triggers; and (4) modifying emotion-driven behaviours (e.g. hypervigilance, withdrawal). The intervention spanned a minimum of 14-weeks and a maximum of 20-weeks; the first 10 sessions occurred on a weekly basis, while sessions 11-12 occurred on a fortnightly basis in order to facilitate the ending of the intervention. Each tCBT session followed a similar format and involved completing the HADS, a brief weekly review, a homework review, a core session exercise and setting homework. At the end of each session participants were given a corresponding chapter from the UP client workbook (Barlow et al., 2010). These chapters ranged between 9 and 23 pages in length. Two-page session summaries were also created as an alternative for participants who could not tolerate reading these lengthy chapters (see appendix 10 for an example). A brief description of the session-by-session aims and content of the tCBT intervention is provided below.

3.6.1 Session 1: 'Getting motivated and setting goals for treatment'

The aim of session 1 is to discuss any ambivalence about behaviour change, identify the pros and cons of change and develop specific treatment goals. At the end of the session participants are asked to finish completing a goal setting worksheet for homework.

3.6.2 Session 2: 'Understanding emotions'

The aim of session 2 is to discuss the function of emotions, and introduce the three main components of an emotional experience (thoughts, emotions/physical sensations, and behaviours). A recent emotion-provoking experience or situation is reviewed in the session and discussed in terms of these components. At the end of the session participants are asked to begin monitoring emotional experiences that occur during the week using a worksheet.

3.6.3 Session 3: 'Recognising and tracking emotional behaviours'

The aim of session 3 is to discuss how emotional experiences influence current and future behaviours. Participants begin to identify the triggers to their emotional experiences, as well as their responses, and the short- and long-term consequences of these responses. At the end of the session participants are asked to begin monitoring the triggers and consequences of their responses to emotional experiences over the coming week using a worksheet.

3.6.4 Sessions 4-5: 'Learning to observe experiences'

The aims of sessions 4 and 5 are for participants to develop skills that will enable them to observe their emotional experiences in a present-focussed and non-judgmental way. Participants practice brief mindfulness (session 4) and emotion induction (session 5) exercises and select a cue (such as their breath) and practice using this cue to anchor them in the present moment. At the end of each session

participants are asked to practice either the brief mindfulness exercise (session 4) or mood-induction and anchoring exercises (session 5) during the coming week.

3.6.5 Sessions 6-7: 'Understanding thoughts: Thinking the worst and overestimating the risk'

The aims of sessions 6 and 7 are for participants to develop a greater awareness of how they interpret or appraise situations, and how thoughts influence emotional responses. Participants learn to identify negative automatic appraisals or 'thinking traps' such as 'jumping to conclusions' and 'thinking the worst' (session 6) and then how to evaluate these appraisals and generate alternatives (session 7). For homework, participants are asked to practice either identifying their negative automatic appraisals (session 6) or generating alternatives to these (session 7).

3.6.6 Session 8: 'Understanding behaviours: Avoiding your emotions and emotion driven behaviours'

The aim of session 8 is to discuss emotion-driven behaviours (EDBs) and how they influence our emotional experience. Participants are assisted to identify their own patterns of emotional avoidance and maladaptive EDBs. At the end of the session participants are asked to continue monitoring their emotional avoidance and EDBs and practice employing behaviours to counter these (e.g. if feeling tired, going for a walk rather than to bed) over the coming week.

3.6.7 Session 9: 'Understanding and confronting physical sensations'

The aim of session 9 is to discuss how physical sensations can influence thoughts and behaviours, and vice versa. Participants are supported to identify internal physical sensations associated with their emotions and then to conduct a series of interoceptive exposure exercises designed to elicit different physical sensations, which mimic

symptoms of anxiety and/or depression. For homework, participants are encouraged to repeatedly practice these exercises so they become more aware of their physical sensations and develop an increased tolerance to these symptoms.

3.6.8 Sessions 10-11: 'Facing emotions and feared situations'

The aim of sessions 10 and 11 is to create an 'emotion avoidance' hierarchy that contains a range of situations designed to provoke strong emotional responses. The therapist assists participants to gradually confront these situations and modify their responses to their emotions using the skills learnt during treatment (e.g. present-focused awareness, cognitive reappraisal). At the end of each session participants are encouraged to systematically work through their hierarchy of exposures during each fortnight.

3.6.9 Session 12: 'Accomplishments, maintenance, and relapse prevention'

The aim of session 12 is to review the key concepts and skills covered during treatment, evaluate treatment progress and areas for improvement and set short- and long-term goals for maintaining treatment gains.

3.7 Adaptations made to the UP

It was necessary to make some adaptations to Barlow et al's (2011) UP in order to account for a British, older audience, as the manual was developed in the United States for working-age people. In line with other initial adaptations to the UP manual (Ehrenreich et al, 2009; Ehrenreich-May & Bilek, 2012; Ellard et al, 2012) these modifications were purposefully minimal in order to be faithful to the UP's theoretical focus and to enable areas requiring more extensive modification in the future to be systematically identified. Table 3

summarises the adaptations made for a UK audience and those made for an older population.

Table 4: Summary of adaptations made to the UP

Adaptations for a UK audience	**Adaptations for an older population**
Americanisms (e.g. sidewalk) substituted with British alternatives (e.g. pavement)	Vignettes and examples adapted to be more developmentally appropriate
Minor spelling changes made e.g. behavior to behaviour	Vignettes and examples modified to account for the greater incidence of comorbid depression symptoms among older adults
	Cautionary statements added into session 9 regarding conducting interoceptive exposures where physical health difficulties exist
	Location of treatment flexible depending on mobility/carer needs
	2-page session summaries created to aid retention of key themes and content
	Tape recordings of sessions and enlarged versions of handouts provided to accommodate sensory impairments
	Where appropriate family members/carers involved in the planning and implementation of homework tasks

Minor changes were made to the language and spelling of words to account for a British audience (e.g. Americanisms such as 'sidewalk' were substituted with British alternatives). Vignettes and examples were adapted to be more developmentally appropriate. For instance, references to work-life scenarios (e.g. doing presentations) were replaced with references to voluntary work, caring roles and attending social groups and day-centres. Vignettes and examples were also modified to account for the greater incidence of comorbid depression symptoms seen in older adults. For example, more references to and examples of depressive type thoughts, feelings and behaviours were included. Furthermore, in line with recommendations described in Section 2.10 some practical adaptations were also made. For example, the location of treatment was flexible depending on the participants mobility/carer needs; 2-page session summaries were created to aid retention of key themes and content; tape recordings of sessions and enlarged versions of handouts were provided where required to accommodate sensory impairments; and where appropriate family members/carers were recruited to aid with the planning and implementation of homework tasks. Finally, where required protocol deviations such as postponing a session in order to address crisis issues that arose during the weekly review were made.

3.8 7-week delayed-treatment group

Participants randomised to the 7-week delayed-treatment group received a brief telephone call each week during the waiting period and completed the HADS in order to monitor risk and symptom deterioration. Participants allocated to this arm also received TAU (e.g. CMHT appointments, case reviews, psychotropic medication changes) during this time. At the end of 7-weeks, participants in the delayed-treatment arm crossed over into the treatment arm and received the tCBT intervention.

3.9 Therapists and supervision arrangements

Study therapists included a trainee (chief investigator) and qualified clinical psychologist. The therapists completed the initial screening assessments, brief weekly phone-calls (to those randomised to the delayed-treatment arm) and the tCBT intervention. All therapists were trained in administering the UP via a training DVD (Barlow, Farchione, Boisseau & Ellard, 2011) and therapist guide produced by Barlow et al. (2011). Clinical supervision was provided by an experienced, independent CBT therapist within the MHOA&D CAG and occurred in a group format, once a month for 2-hours.

3.10 Treatment adherence

Treatment adherence was monitored during monthly supervision sessions and study therapists were provided with a checklist for each session to facilitate the consistency of the session format and content (see appendix 11 for an example). Participants were asked to provide verbal and written consent for their tCBT sessions to be audio recorded to facilitate the formal assessment of treatment adherence by an additional independent clinical psychologist within the MHOA&D CAG. One participant dropped out before the intervention began so was excluded from this process. One participant declined due to concerns they would feel uncomfortable and one participant initially gave and then withdrew their consent due to concerns that they were not be able to talk openly during the sessions. One session from each of the remaining 13 participants (8%) was randomly selected to assess adherence to the treatment protocol. A treatment adherence checklist was created for each of the 12 tCBT sessions which broadly asked the rater to indicate the extent to which the core content of each session - weekly review, core session exercise(s) and homework assignment(s) - were discussed according to 4 possible options: 'yes', 'partially', 'no' or 'unclear' (see appendix 12 for an example).

3.11 Data analysis strategy

3.11.1 Baseline data

Demographic and clinical characteristics analyses

Independent group *t*-tests and chi-squared tests were used to examine any between-group differences in baseline demographic and clinical characteristics including age, sex, years of education, highest level of occupational attainment and pre-treatment symptom severity (according to the CORE-10 and HADS subscale scores).

3.11.2 Efficacy data

Data imputation

The study aimed to continually assess any participants who dropped out at the intervals outlined above (see Table 2). However, where this was not possible, the imputation method of 'last observation carried forward' was used (Streiner, 2002).

Controlled data analyses

Intention-to-treat (ITT) analyses were conducted. Independent group *t*-tests were used to analyse between-group differences in change scores (pre-1 minus pre-2; for the delayed group, vs. pre1 minus mid-treatment; for the immediate group). Treatment condition was the between-subjects independent variable (immediate-treatment plus TAU vs. delayed-treatment plus TAU) and time was the within-subjects independent variable (pre- vs. mid-treatment). The dependent variables were the change in scores on the self-rated outcome measures (HADS, CORE-10).

Uncontrolled data analyses

Analyses combined participant data from the immediate treatment condition with those who crossed over into the treatment condition after the 7-week delay-period. A one-way, repeated measures ANOVA was employed, with time as a within-subjects variable (pre- [pre1 if

immediate, pre2 if delayed] vs. mid- vs. post-treatment). Post-hoc pairwise comparisons were conducted to explore statistically significant main effects and interaction terms (p<0.05).

Effect sizes

Cohen's *d* mean standardised difference (MSD) effect sizes were calculated for each self-report measure of anxiety and depression symptoms (CORE-10 and HADS subscales). The MSD was calculated using the mean difference in the outcome score between pre- and post-treatment divided by the pooled standard deviation.

$$d = \frac{(\text{Mean}_{\text{pre}} - \text{Mean}_{\text{post}})}{SD_{\text{pooled}}}$$

The effect sizes were then interpreted according to Cohen's (1988) guidelines where effects of 0.2, 0.5 and 0.8 are described as 'small', 'medium' and 'large' respectively.

Reliable Change

The Reliable Change Index (RCI) was used to calculate whether individual change scores on the HADS subscales were clinically significant.

Treatment adherence

Ratings from the treatment adherence checklist were analysed using descriptive statistics.

3.11.3 Feasibility data

The feasibility of the tCBT intervention was evaluated according to attrition rates due to practical reasons (e.g. difficulty in attending due to mobility issues or physical health problems), which were analysed using descriptive statistics.

3.11.4 Acceptability data

The acceptability of the tCBT intervention was evaluated according to attrition rates due to dissatisfaction with the intervention, homework compliance and client-rated satisfaction data collected from the DSQ. Attrition rates due to dissatisfaction were analysed using descriptive statistics. Quantitative satisfaction data from the DSQ (items 3-10) were analysed using descriptive statistics. Qualitative data from the DSQ (item 11) were analysed using thematic analysis to explore common themes, in accordance with guidelines proposed by Braun and Clarke (2006)..

Participants session-by-session homework compliance was recorded as either 'yes' (completed all aspects of homework), 'partially' (some but not all aspects of homework were completed), or 'no' (homework was not completed). Overall percentages of homework compliance, partial compliance and non-compliance were calculated for each participant.

4. Results

4.1 Baseline data

4.1.1 Participant flow

One hundred and five older people were referred to the study, and of these 52 were unsuitable, 28 were potentially suitable but declined to take part in the study, 25 completed an initial screening assessment and of these 9 were assessed to be unsuitable and 16 were assessed as suitable and consented to take part in the trial. Figure 4 illustrates participants' enrolment and flow through the study, including a breakdown of the reasons participants were excluded from the trial at each stage. Eight were randomised to the immediate-treatment condition and 8 to the delayed-treatment condition. One participant was later excluded from the trial and analysis on discovery of an existing Dementia diagnosis. ITT analyses were conducted using data from the remaining 15 participants.

Table 5: Overall demographic characteristics of the sample

		Frequency				**Frequency**	
Demographic	**Type/Level**	***n***	**(%)**	**Demographic**	**Type/Level**	***n***	**(%)**
Sex	Male	7	46.70	Highest occupation	Professional	4	26.70
	Female	8	53.30		Manager/ Director	3	20.00
Age	Mean (SD)	75.53 (8.31)	-		Administrator	3	20.00
Years of education	Mean (SD)	12.47 (3.20)	-		Skilled trade	2	13.30
Ethnicity	Caucasian	13	86.70		Sales/ Customer service	2	13.30
	Asian	2	13.30		Technician	1	6.70
Marital status	Married	10	66.70	History of anxiety &/or depression	Yes	13	86.70
	Widowed	2	13.30		No	2	13.30
	Divorced	1	6.70	Previous psychological treatment	Yes	5	33.30
	Single	1	6.70		No	10	66.70
	Co-habiting	1	6.70	Concomitant psychotropic medication	Yes	11	73.30
					No	4	26.70

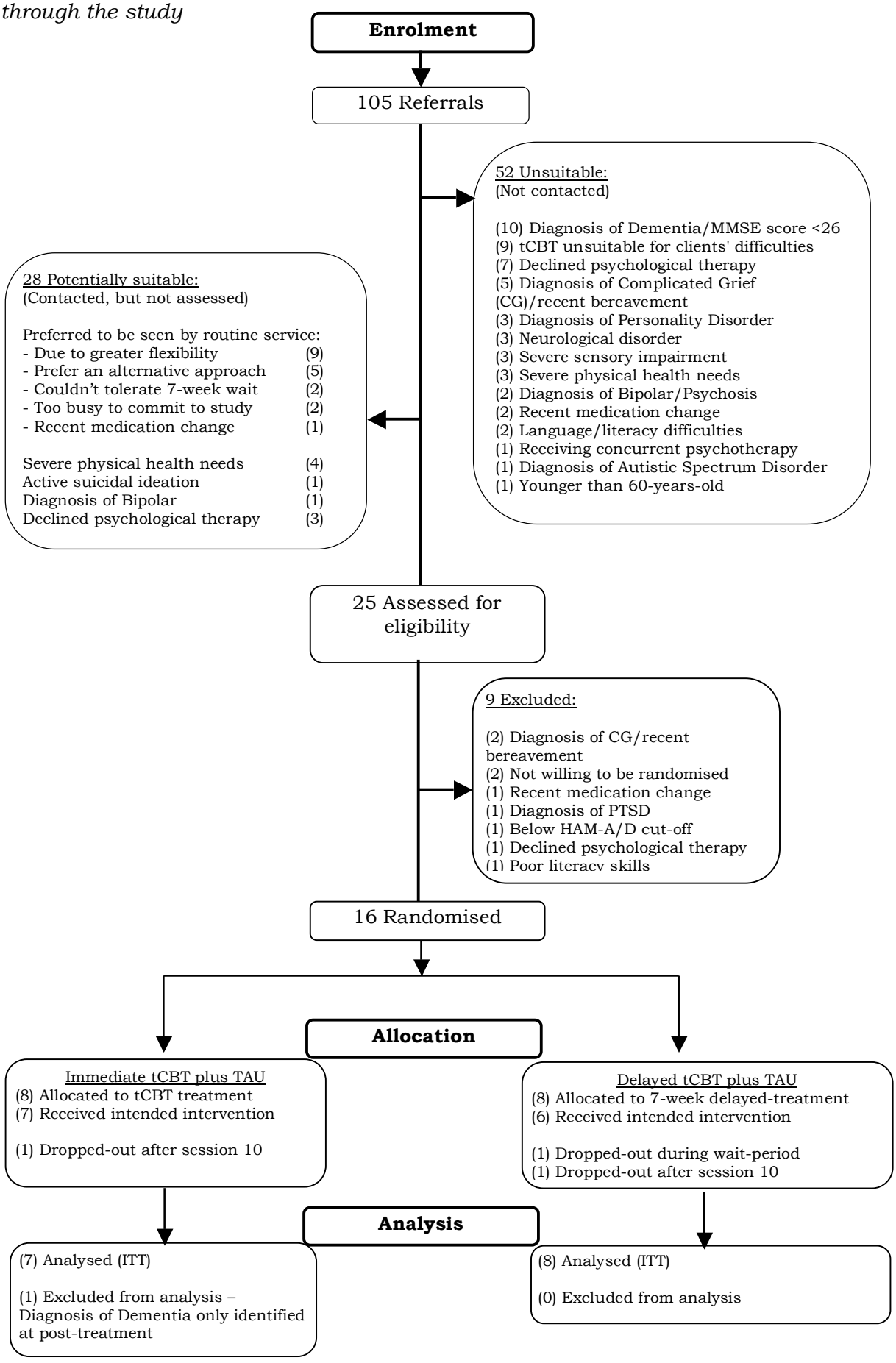
Table 6: Overall frequency of primary, secondary and additional diagnoses.

	Frequency	
	n	**(%)**
Primary diagnosis	15	100.00
Major Depression	8	53.30
GAD	5	33.30
SAD	1	6.70
Mixed anxiety and depression	1	6.70
Secondary diagnosis	13	86.67
GAD	7	46.70
Major Depression	6	40.00
Additional diagnoses	4	26.67
Agoraphobia without Panic	2	13.30
Panic without Agoraphobia	1	6.70
SAD	1	6.70

Table 7: Overall severity of anxiety and depression symptoms at pre-treatment

Measure	**Mean (range)**	***SD***
HADS depression scale	12.47 (Moderate)	4.52
HADS anxiety scale	12.00 (Moderate)	4.09
CORE-10	1.81 (Moderate)	0.73

Figure 4: CONSORT diagram illustrating participant enrolment and flow through the study



4.1.2 Demographic and clinical characteristics analyses

Independent group *t*-tests were used to examine between-group differences in baseline demographic and clinical characteristics including age, sex, years of education, level of occupational attainment and pre-treatment symptom severity (according to baseline CORE-10 and HADS scores).

In terms of interval/ratio data variables (age, years of education, pre-treatment symptom severity), initial tests of normality and homogeneity were conducted. Each of these variables were non-significant, with the exception of 'years of education' (p=0.03) where the normality assumption was violated, therefore non-parametric analyses were conducted instead.

Independent group *t*-tests showed that there were no significant differences in age or scores on any measure of symptom severity at baseline between the immediate- and delayed-treatment groups (see Table 8).

There was also no significant difference in years of education between the immediate- and delayed-treatment groups (U = 22.5, N_1 = 7, N_2 = 8, p = .54). There was no relationship between sex or highest level of occupational attainment and experimental condition (immediate vs. delayed treatment).

Table 8: Means, SDs and frequencies for baseline demographics and characteristics

	Immediate tCBT plus TAU (n=7)		**Delayed tCBT plus TAU (n=8)**					
Demographic	**Mean**	***SD***	**Mean**	***SD***	***n***	***t***	***df***	***p***
Age	76.71	7.25	74.50	9.50	15	-0.50	13	0.31
Years of education	12.14	3.39	12.75	3.24	15	*	*	*
CORE-10	1.97	0.68	1.96	0.56	15	0.28	13	0.49
HADS Anxiety	12.71	3.86	12.71	3.40	15	0.17	13	0.44
HADS Depression	12.38	4.00	11.25	3.32	15	0.84	13	0.21
(Sex/Occupation)	**Frequency *n* (%)**		**Frequency *n* (%)**		***n***	**X_2**	***df***	***p***
Male	3(42.90)		4(50.00)		15	0.77	1	0.39
Female	4(57.10)		4(50.00)		15			
Manager/Director	1(14.30)		2(25.00)		15	4.62	5	0.23
Professional	1(14.30)		3(37.50)		15			
Associate professional/technician	0(0)		1(12.50)		15			
Administrative	2(28.60)		1(12.50)		15			
Skilled trade	1(14.30)		1(12.50)		15			
Sales/Customer service	2(28.60)		0(0)		15			

** Years of education – Mann-Whitney U*

4.2 Efficacy data

4.2.1 Controlled analyses

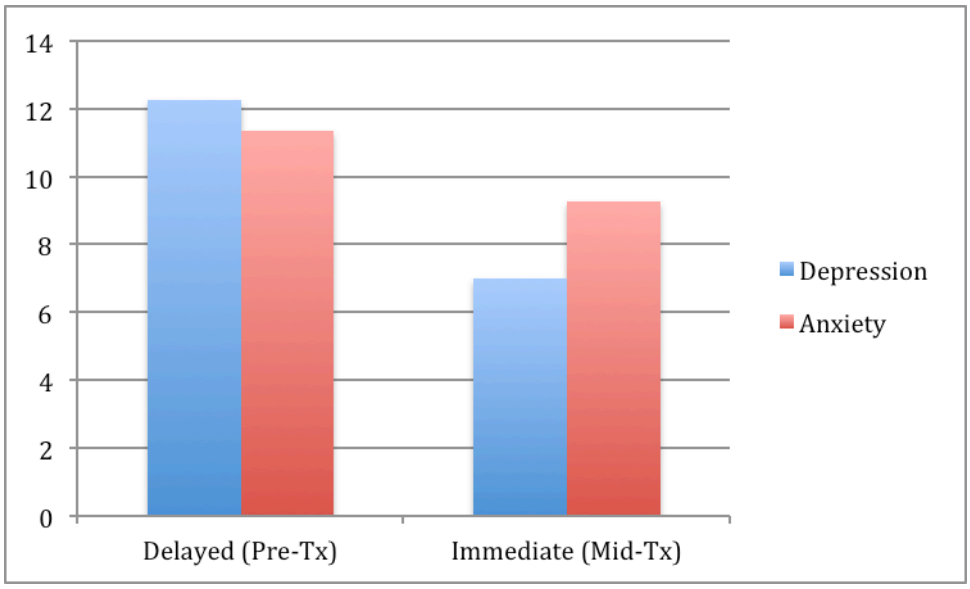
Independent group *t*-tests were used to examine between-group differences in change scores (pre1 minus pre2 for the delayed condition; pre1 minus mid-treatment for the immediate condition; see Table 2) on the self-rated outcome measures (CORE-10, HADS). Tests for normality and homogeneity of variance were again non-significant ($p>0.05$).

Independent group *t*-tests revealed that there were no significant differences in mean change scores on the CORE-10 or HADS anxiety between the immediate- and delayed-treatment groups (see Table 9). However, there was a significant difference in mean change scores on the HADS depression subscale between the immediate and delayed treatment groups.

Table 9: Mean change scores and SDs from the controlled analyses

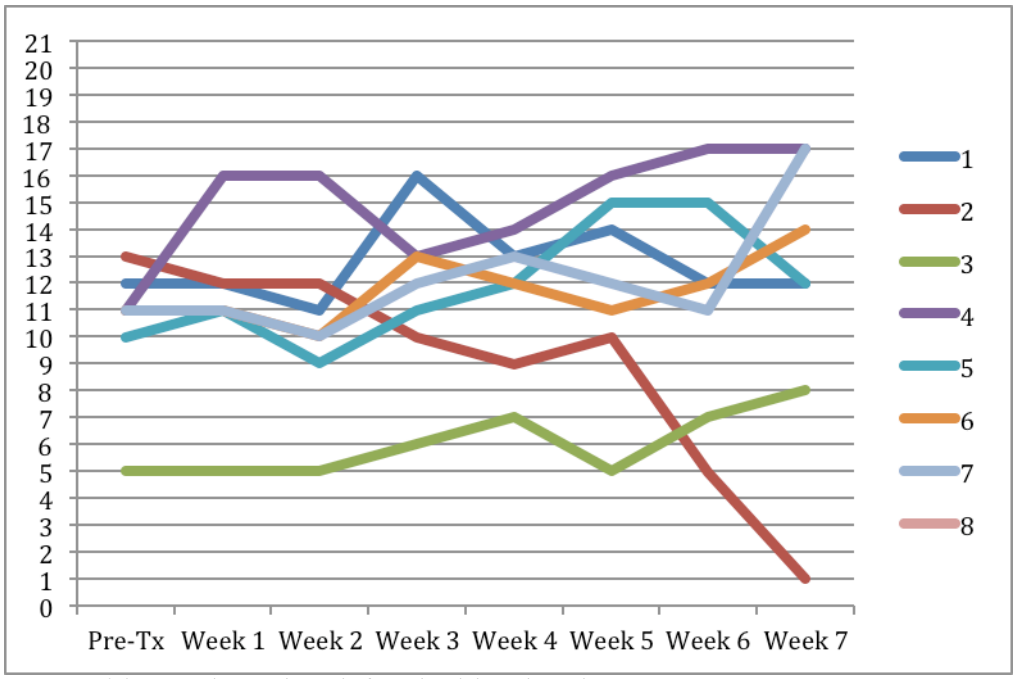
	Immediate tCBT plus TAU (n=7)		**Delayed tCBT plus TAU (n=8)**				
Outcome measure	**Mean**	***SD***	**Mean**	***SD***	***t***	***df***	***p***
CORE-10	0.50	0.63	0.30	0.69	0.59	13	0.29
HADS Anxiety	3.43	4.24	1.00	4.66	1.05	13	0.16
HADS Depression	5.71	3.25	-1.00	5.73	2.73	13	0.01

Figure 5: Comparison of mean depression and anxiety scores (HADS) in the delayed- and immediate-treatment conditions (Pre- vs. Mid-Treatment)



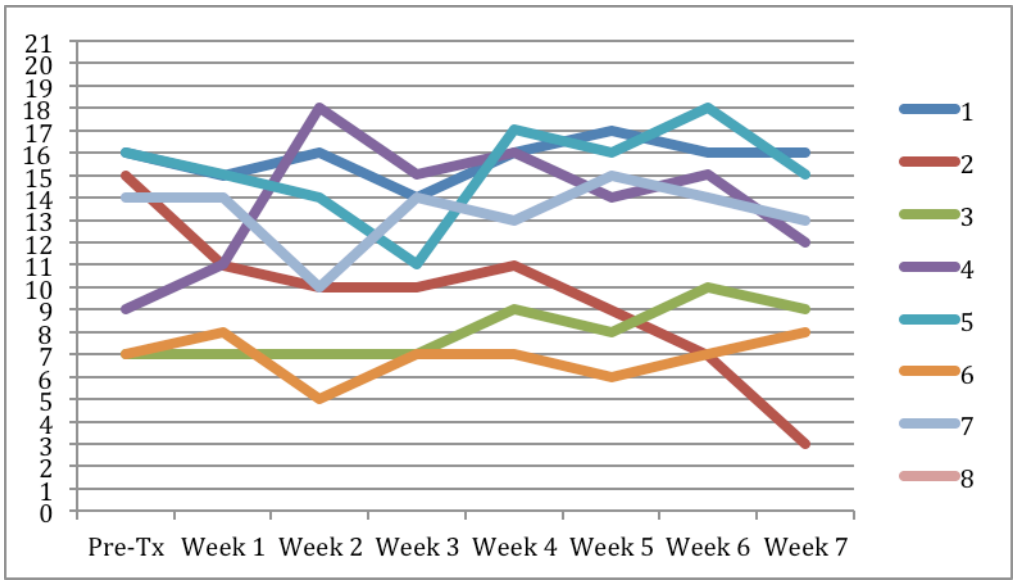
Figures 6 and 7 depict the week-by-week depression and anxiety symptom scores (HADS) for participants during the 7-week delay-phase (n=8).

Figure 6: Week-to-week depression symptom scores (HADS) for participants during the 7-week delay-treatment phase (n=8)



Note: Participant 8 dropped-out before the delay phase began.

Figure 7: Week-to-week anxiety symptom scores (HADS) for participants during the 7-week delayed-treatment phase (n=8)



Note: Participant 8 dropped-out before the delay phase began.

4.2.2 Uncontrolled analyses

A one-way repeated measures ANOVA was conducted on self-reported symptoms of anxiety and depression at pre- (pre1 for immediate group, pre2 for delayed group) vs. mid- vs. post-treatment. As shown in Table 10, there were statistically significant main effects of time (pre- vs. mid- vs. post-treatment) on the CORE-10 $F(2,28) = 4.31$, $p<0.05$, HADS anxiety $F(2,28) = 4.45$, $p<0.05$, and HADS depression $F(2,28) = 8.19$, $p<0.01$ subscales.

Employing the Least Significant Difference (LSD) post-hoc test, significant differences were found pre- to post-treatment, but not pre- to mid- treatment or mid- to post-treatment on the CORE-10. In terms of the HADS anxiety subscale, significant differences in self-reported symptoms of anxiety were found pre- to mid-treatment and pre- to post-treatment, but not mid- to post-treatment. Similarly, in terms of the HADS depression subscale, significant differences in self-

reported symptoms of depression were found pre- to mid-treatment and pre- to post-treatment, but not mid- to post-treatment.

4.2.3 Effect sizes

Pre- to post-treatment Cohen's *d* effect sizes (Cohen, 1998) were calculated. Table 10 illustrates that 'medium' effect sizes were achieved on CORE-10, HADS anxiety and depression subscales.

Table 10: Magnitude of the effect sizes achieved on the CORE-10 and HADS subscales pre- to post-treatment*

Outcome measure	**Cohen's *d***	**Magnitude**
CORE-10	0.63	'Medium'
HADS Anxiety	0.66	'Medium'
HADS Depression	0.78	'Medium'

**Where d=0.2 – 'small', d=0.5 – 'medium', d=0.8 - 'large'.*

Table 11: Results of the one-way ANOVAs and pairwise comparisons

	Pre-		**Mid-**		**Post-**		**Main effect**			**Post-hoc**	
Outcome measure	**Mean**	***SD***	**Mean**	***SD***	**Mean**	***SD***	***F***	***df***	***p***	**Comparison***	***p***
CORE-10	1.81	0.73	1.56	0.92	1.27	0.97	4.31	2,28	0.02	pre- vs. mid-	0.14
										pre- vs. post-	0.03
										mid- vs. post-	0.09
HADS Anxiety	12.00	4.08	9.27	5.26	8.47	6.32	4.45	2,28	0.02	pre- vs. mid-	0.01
										pre- vs. post-	0.03
										mid- vs. post-	0.53
HADS Depression	12.47	4.52	9.27	5.65	8.00	6.68	8.19	2,28	0.00	pre- vs. mid-	0.01
										pre- vs. post-	0.00
										mid- vs. post-	0.18

4.2.4 Reliable change

The Reliable Change Index (RCI; Jacobson, Follette & Revenstorf, 1984) was used to calculate the extent to which each participant's change score (pre-to post-treatment) as measured by the HADS subscales were clinically significant. Table 11 details the proportion of participants whose scores fell within the 'non-clinical range, 'reliably improved', 'reliably deteriorated' and were classifiable as 'recovered'. In terms of the HADS anxiety subscale, 57% of participants scored within the 'non-clinical range, 43% were classifiable as 'reliably improved', 36% as 'recovered' and 7% demonstrated 'reliable deterioration'. In terms of the HADS depression subscale, 71% were classifiable as within the 'non-clinical range' and 'reliably improved', 64% as 'recovered' and 13% demonstrated 'reliable deterioration'.

Table 12: Percentages of participants non-clinical range, reliably improved, reliably deteriorated and recovered pre- to post-treatment

Measure	***n****	**Non-Clinical Range *n* (%)**	**Reliably Improved *n* (%)**	**Reliably Deteriorated *n* (%)**	**Recovered *n* (%)**
HADS Anxiety	14	8(57)	6(43)	1(7)	5(36)
HADS Depression	14	10(71)	10(71)	2(13)	9(64)

** Excludes 1 participant who dropped out before the intervention began*

'Non-clinical range'- defined by a score <8 on the HADS subscales

'Reliable improvement' - defined by a RCI score ≤-1.96

'Reliable deterioration' - defined by a RCI score ≥1.96

'Recovered' – defined by a score below clinical cut-off and ≤-1.96 on the RCI

4.2.5 Treatment adherence

All 12 of the randomly selected tCBT sessions reviewed using the checklist were rated as 'fully adherent' in terms of completing a weekly and homework review, implementing the appropriate core exercise and setting related homework tasks.

4.3 Feasibility data

In the 3 cases where participants dropped out of the intervention, these were related to the feasibility of beginning or continuing with the intervention. Two participants dropped out following session 10 (of 12), 1 due to a sudden deterioration in their physical health, and 1 because they were struggling to engage in the intervention due to the intensity of their anxiety. The third participant dropped out during the delayed-treatment phase, before receiving the intervention, as they did not feel ready to engage in psychological therapy.

4.4 Acceptability data

4.4.1 Attrition

In the 3 cases where participants dropped out of the intervention, none of these were for reasons of dissatisfaction with the tCBT intervention.

4.4.2 Feedback from the Discharge Satisfaction Questionnaire (DSQ)

All of the treatment completers (n=12) completed the DSQ. Data from items 3 to 10 on the DSQ were analysed using descriptive statistics. These are provided below in Table 13.

Table 13: Descriptive statistics for Items 3 to 10 of the DSQ.

Item	Mean*	SD
Q3. Were you satisfied with the wait time for therapy?	9.42	1.00
Q4. Were you satisfied with the location of your therapy?	9.75	0.87
Q5. Did you feel your therapist treated you with dignity and respect?	9.83	0.58
Q6. Did you feel your therapist understood your experiences?	9.33	1.07
Q7. Did you feel that you had enough time to explore your experiences?	9.50	0.90
Q8. Did your therapist help you to set out the goals for your therapy?	9.50	1.24
Q9. Overall did the sessions with your therapist help you move towards your goals?	9.08	1.44
Q10. Overall did the sessions with your therapist help you to better cope with your life?	9.33	1.37

** '0=Not at all, 10=Definitely'*

Overall, satisfaction with the therapy (as captured by items 3 to 10 of the DSQ) was rated very positively. The mean score on every item was greater than 9 out of 10 (where '0' = 'Not at all' and '10' = 'Definitely'). There was very little variation between the mean responses endorsed for each item. However, the most positively endorsed aspect of the therapy was its location and feeling treated with dignity and respect by the therapist. The least positively endorsed aspect of the therapy was the extent to which the therapists helped the client move towards their goals, however, this rating was still high (9.1/10).

Of the 12 treatment completers who completed the DSQ, two-thirds (n=8) provided qualitative feedback. Participants were invited to *"Tell us anything else that you would like us to know. Including any other comments about the service you received, your experience of your therapist or more information on any of the questions that you have answered already"*. These responses were transcribed and distilled

into 5 core themes, which related to "therapist characteristics", "therapeutic relationship", "gratitude", "outcomes" and "content" of the tCBT intervention. An additional theme was also assigned to "miscellaneous" responses (see Table 14).

Table 14: Themes and frequencies of related responses (n) for Item 11 of the DSQ.

Theme	**n**
"Therapist characteristics"	5
"Outcomes"	5
"Gratitude"	4
"Therapeutic relationship"	2
"Content"	2
"Miscellaneous"	2

Most of the qualitative feedback related to comments about therapist characteristics and the outcomes of the intervention. Participants highlighted positive qualities in their therapist. For example, one participant commented *"She was very kind and helpful"* and another *"She is a genuine caring person"*. Participants' feedback regarding the outcomes of the intervention was also positive. Within this theme some participants attributed a positive outcome to the therapist (e.g. *"She taught me how to live again"* and *"Her insight has given me a new lease of life")*, whilst others attributed a positive outcome to the intervention (e.g. *"The sessions have helped me to cope better with my anxiety"* and *"The treatment has given me my confidence back and I feel back to my old self"*).

Another popular theme related to comments expressing gratitude. Examples of comments subsumed within this theme include *"I appreciated talking to someone"*, *"I am sincerely grateful for the helpful sessions"*, *"The help I have had I would never have thought possible"* and *"I feel very satisfied with the therapy. I could not have wished for a better therapist"*.

Other themes to emerge from participants' feedback related to the therapeutic relationship and content of the intervention. In terms of the therapeutic relationship these comments were again positive, with one participant mentioning *"From my first meeting with [therapist] I felt at ease, also a good sense of trust on my part as the relationship built up,"* and another *"She understood where I was coming from and did not presume I fit the stereotype of your average Asian woman"*.

In terms of content this theme contained one positive and one negative comment. One participant commented positively about the intervention as a whole: *"The exercises really helped me to evaluate my old habits and work out what I could do instead. The mindfulness exercise was also helpful for stress and I liked it because it was not too long, so feasible to do regularly"*. Another spoke negatively about the materials they had received: *"I found the hand-outs very confusing and repetitive. It took a great deal of concentration to understand what was being said – and that was only after 2 or 3 times! I thought that they were unnecessarily complex and simpler language would have been more understandable"*.

The final theme "miscellaneous" was assigned to two extraneous comments that did not directly relate to the therapist or intervention received. For example, one participant commented *"She will, I am sure do exceptionally well in her career"*, and another *"I used to suck a dummy continuously til it was hidden from me until the age of four so I am told"*.

4.4.3 Homework compliance

The percentage of full, partial and non-compliance with respect to homework across the tCBT intervention was calculated for each participant (n=14). Overall, the average proportion of homework tasks partially or fully completed was 76%. Within this, the proportion of fully completed homework tasks was 58% and the proportion of partially completed homework tasks was 18%. The proportion of non-compliance was 24%.

4.5 Summary of results

No significant differences in participants' symptom scores were found between the immediate and delayed-treatment groups prior to the commencement of treatment. However, when participants halfway through the tCBT intervention (immediate-treatment), were compared with those just about to start the intervention (delayed-treatment) there were significant differences found in participants' depression symptoms, but not anxiety or general mood symptoms (CORE-10).

There were significant main effects of time (pre- vs. mid- vs. post-treatment) and post-hoc analyses revealed a significant reduction in scores pre- to post-treatment on the CORE-10, and pre- to mid-treatment and pre- to post-treatment on the HADS anxiety and depression subscales. Furthermore, medium pre- to post-treatment effect sizes were achieved on all the self-report measures.

The percentage of participants scoring within the 'non-clinical range' on the HADS subscales increased to 57 (anxiety) and 71% (depression) at post-treatment. Furthermore, 43% (anxiety) to 71% (depression) of participants achieved reliable improvement in their symptoms and between 36% (anxiety) and 64% (depression) were classifiable as 'recovered' at post-treatment.

Three participants dropped-out of the intervention, and in all cases the reasons for attrition were not due to the feasibility of or

dissatisfaction with the intervention. Participant feedback was overwhelming positive, especially regarding the location of the intervention (often the participant's home) and the extent to which the participant felt they were treated with dignity and respect. Homework compliance was high (76%), suggesting that the majority of homework tasks were perceived as acceptable and feasible to complete.

5. Discussion:

The primary aims of this study were to ascertain preliminary estimates of the efficacy, feasibility and acceptability of delivering tCBT to older people with symptoms of depression and anxiety in comparison to a 7-week delayed-treatment condition. This section will begin by discussing the main findings in relation to the hypotheses and wider literature. It will then move on to consider the implications of the study findings. Finally, it will address methodological issues and areas of future research.

5.1 Discussion of main findings in relation to hypotheses and previous research

5.1.1 How efficacious is tCBT for older people with anxiety and depression?

It was hypothesised that the tCBT intervention would significantly reduce symptoms of anxiety and depression among older people relative to a delayed-treatment control condition. There was partial support for this hypothesis. Outcomes for those in the immediate-treatment group were superior to those in the delayed-treatment group at the mid-intervention point in terms of self-reported depression symptoms, but not in terms of self-reported anxiety and overall mood symptoms. There are a few possible explanations for the failure to find significant between-group differences in anxiety or overall mood symptoms, the most likely reason being because the study was underpowered to detect between-group differences. Another factor is the sensitivity of the outcome measures used. For example, there is some evidence to suggest that the HADS is poorer at detecting changes in anxiety symptoms in older adults (Davies et al., 1993), perhaps because of the complicated interaction between somatic and mood symptoms. This poorer sensitivity could also partly explain the smaller rates of 'recovered' (36 vs. 64%) and 'reliably improved' (43 vs. 71%) found here in terms of anxiety relative to

depression symptoms. Another possible explanation for this differential outcome is that the more active components of the treatment protocol (e.g. cognitive restructuring, confronting physical sensations, graded emotional exposure) were covered during the second half of treatment, after the mid-treatment assessment when the between-group differences were analysed. It is plausible that these treatment components are particularly beneficial for tackling fears and anxiety symptoms and therefore, this finding may merely represent an artefact of the point at which between-group data were analysed, rather than indicating reduced efficacy of the tCBT intervention in relieving anxiety symptoms.

It was also hypothesised that the tCBT intervention would significantly reduce self-reported symptoms of anxiety and depression in older people pre- to post-treatment. Evidence was found to support this hypothesis. This finding replicates previous trials examining the efficacy of tCBT for emotional disorders (Titov et al., 2011; McEvoy & Nathan, 2007; Ellard et al., 2010; Farchione et al., 2012) and extends the body of research demonstrating that efficacious adaptations of the UP (Barlow et al., 2011) to other age groups can be achieved (Ehrenreich et al., 2009; Bilek & Ehrenreich-May, 2012).

Medium within-group effect sizes were obtained on all three self-report outcome measures, which were not as large as those reported in trials examining the UP with working-age adults (Beck Depression Inventory-II [BDI-II] d=0.95, BAI d=1.13; Farchione et al., 2013) or a recent group CBT trial for comorbid anxiety and depression in older people (Geriatric Depression Scale [GDS] d=0.98, Geriatric Anxiety Inventory [GAI] d=0.95; Wuthrich & Rapee, 2013), although it is difficult to reliably compare these effect sizes as the study was underpowered.

More than half of the participants dropped to within the non-clinical range in terms of their self-reported symptoms of anxiety (57%) and depression (71%) following the tCBT intervention. Furthermore, the

proportion of participants who achieved clinically reliable change (as indicated by the RCI) (43% anxiety; 71% depression) and 'recovery' (36% anxiety; 64% depression) was also promising. The rates of recovery and reliable change achieved here are comparable to those achieved in trials examining the UP (Barlow et al., 2011) with working-age adults. For instance, in an evaluation of the UP (resembling the version adapted for the current study) Ellard et al. (2010) reported that 60% of participants scored within the non-clinical range on at least one outcome measure and Farchione et al. (2013) reported rates of 50%. Furthermore, these results are comparable to those reported in a recent RCT examining group CBT for comorbid anxiety and depression in older people (Wuthrich & Rapee, 2013), in which 42% of participants in the intervention group were classifiable as within the 'non clinical range' (although this was based on clinician- rather than self-report measures) and 73% showed reliable improvement in their symptoms pre- to post-treatment. These comparisons with similar studies are tentative as they utilised different outcome measures, but are none-the-less encouraging for this pilot study.

It is also important to acknowledge that two participants reliably deteriorated either in terms of their depression and/or anxiety symptoms. Whilst neither of these participants identified the intervention as contributing to their deterioration, it is important to consider the reasons underlying this. One participant (who showed deterioration in their depression scores) completed their post-treatment outcome assessment almost a week after their final session (due to the availability of the outcome assessors) and during this time experienced significant interpersonal difficulties, which affected their scores. This participant was followed-up almost 2-months later and their scores had decreased to within the non-clinical range. They were subsequently referred for psychodynamic psychotherapy due to encountering frequent interpersonal difficulties. The other participant to indicate symptom deterioration (on both HADS subscales) had an undiagnosed personality disorder, limited motivation to change,

chronic neuropathic pain and poor physical health, which affected their response to and ability to engage in the intervention. This person reported some treatment gains at the end of therapy (e.g. becoming more aware of their limitations and accepting of their illness), but these were not detectable on outcome measures used in the study. Such treatment gains may not have affected their anxiety or depression in the short-term, but may have a more beneficial effect in the long-term. This participant was subsequently referred for pain management.

The psychotherapy outcome literature suggests that approximately 10% of patients will demonstrate symptom deterioration following treatment (Boisvert & Faust, 2003). The examination of deterioration associated with a therapeutic intervention is complex as it is difficult to ascertain cause and effect (i.e. whether the deterioration would have occurred anyway). However, genuinely harmful therapeutic interventions tend to be associated with high levels of attrition (Lilienfeld, 2007), which was not the case here. Another indicator of genuinely harmful interventions is if significantly more patients exhibit symptom deterioration following treatment compared to those receiving no treatment (Mays & Franks, 1980), this was also not demonstrated here. Therefore, whilst it cannot be concluded that the symptom deterioration which occurred for the two participants described above was caused by the tCBT intervention, it is clear that the UP needs further refinement and evaluation to improve its efficacy and utility to older people with emotional disorders. Some potential ideas as to how the UP might be more successfully refined for this age-group are discussed in section 5.2.2.

5.1.2 How feasible is it to deliver tCBT to older people with anxiety and depression?

It was hypothesised that it would be feasible to deliver the tCBT intervention to older people with anxiety and depression. Evidence was found to support this hypothesis. Overall, the tCBT therapists consistently delivered the intervention as per the adapted protocol to the benefit of the vast majority of participants and there was no evidence of attrition due to practical reasons.

Although the feasibility of delivering different aspects of the intervention was not systematically or independently evaluated, during supervision sessions the study therapists frequently commented that the 'identifying and evaluating automatic appraisals' and 'confronting physical sensations' exercises were particularly challenging to deliver. The therapists often reflected that it was difficult to implement the 'confronting physical sensations' exercise with people who were predominantly depressed and who reported little distress associated with mood-related physical sensations. The challenge of delivering this exercise with an older population was also not surprising given that many suffered with comorbid physical health conditions, such as chronic pain, COPD, and angina, which complicated or prohibited the intentional provocation of symptoms (Evans, 2007; Zeiss, Lewinsohn, Rohde & Seeley, 1996).

It is perhaps also not surprising that 'identifying and evaluating automatic appraisals' was often described as challenging with this age group as only 2 sessions were allocated to tackle these skills in the treatment protocol, however, research suggests that this technique takes longer to implement with older than younger people. Chand and Grossberg (2013) suggest that modification of dysfunctional beliefs can take longer in this age group simply because these have strengthened and become more entrenched over a longer lifetime. There is also some evidence to suggest that older people are genuinely less successful at implementing cognitive reappraisal

techniques than younger people (Opitz, Rauch, Terry & Urry, 2012), perhaps because reappraisal requires cognitive control abilities, which are known to decline with age (Kalisch, 2009). Opitz et al. (2012) found that compared with younger adults (18-22 years), older adults (55-65 years) had greater difficulty using cognitive reappraisal techniques to decrease the intensity of unpleasant emotions. This observation was accompanied by significantly less activation within two areas of the prefrontal cortex (PFC) implicated in cognitive control, and predictive of reappraisal success (the left ventrolateral and dorsal medial PFC).

On reflection, the study therapists and independent clinical supervisor felt that to further improve the feasibility of delivering this protocol to an older audience it might be helpful to include additional content relevant to common age-related concerns (e.g. fear of falling, pain-management, carer wellbeing), place a greater emphasis on delivering behavioural exercises earlier on in treatment and the involvement of family members (where appropriate), allow more time to be spent on thought challenging and mindfulness skills (e.g. 3-minute breathing spaces), simplify and reduce the amount of content presented to handouts/summaries, permit greater flexibility in the delivery of the protocol (e.g. didactic vs. experiential), and slightly increase the length of the intervention. These suggestions echo recommendations within the older adult literature on how to address the specific nuances of late-life mood presentations (e.g. Laidlaw et al.'s [2004] conceptual framework for older people, which advocates for increased focus on physical health, cohort beliefs, and adapting to losses and role transitions), and recommendations discussed earlier about allowing more time for cognitive reappraisal exercises with older people (Chand & Grossberg, 2013; Optiz et al., 2012). There is also evidence to support the involvement of family members when planning homework tasks (Teri et al., 1994) and offering older people a greater number of sessions (where appropriate). For instance, Laidlaw, Thompson, Gallagher-Thompson, & Dick-Siskin (2003) suggest that older people may require between 16 to 20 sessions to

achieve remission of depression symptoms. Furthermore, Pinquart and Sörensen (2001) argue that the often chronic nature of difficulties and stressors in late life require a longer course of treatment than with younger people for whom difficulties/stressors are more often acute and recently acquired. Finally, the request to simplify and reduce the amount of content presented in handouts and session summaries underscores evidence which suggests that older people may benefit from information presented in smaller volumes and a lower reading level than working-age people (Howard, Sentell & Gazmararian, 2006) due to cohort differences in access to higher education and processing speed abilities.

5.1.3 How acceptable is tCBT to older people with anxiety and depression?

It was hypothesised that the tCBT intervention would be acceptable to older people with anxiety and depression. Evidence was found to support this hypothesis. Rates of attrition were low (n=3) and where they occurred were not due to dissatisfaction with the intervention. Another common indicator of acceptability is homework compliance (Scheel, Hanson & Razzhavaikina, 2004), which was high (76%) despite the challenges often posed to older people in completing these tasks (e.g. due to physical constraints and/or carer demands). Participants indicated very high satisfaction with the intervention, and highlighted particular appreciation of the therapists' characteristics, the quality of the treatment they received and the outcomes they gained. These findings are consistent with evidence that suggests that older people often demonstrate better treatment compliance, lower dropout rates, and more positive responses to psychological treatments than younger people (Nierenberg & McColl, 1996; Myers & Harper, 2004).

5.2 Clinical implications

A key motivator for seeking to evaluate the potential efficacy, feasibility and acceptability of applying a tCBT intervention to older people with anxiety and depression is that these disorders frequently co-occur within this population, and are associated with worse physical and mental health outcomes than either disorder alone and a poorer treatment response (Wuthrich & Rapee, 2013). Comorbidity represents a complex clinical conundrum for clinicians and it is not sufficient to randomly amalgamate elements from different disorder-specific protocols to tackle this issue as evidence suggests this reduces their efficacy (Craske et al., 2007). There is consensus that the current efficacy, availability and range of psychological treatments for older people with anxiety and depression need to be improved (Gould et al., 2012a, Gould et al., 2012b, Ghosh, 2009) in order to better serve an aging population, and meet service targets (DoH, 2011).

5.2.1 Implications for the NHS

The current preference within stepped-care mental health services such as IAPT to target overt and diagnostic-exclusive maintaining processes (rather than shared and latent processes) with traditional disorder-specific CBT protocols has several disadvantages. For one, the sheer number of different protocols required to learn is timely, plus it is a challenge to train to implement each of these specific protocols to a high standard. However, therapist skill is key as research consistently demonstrates that the efficacy of any one CBT protocol is positively related to the skill of the individual practitioner (Barber, Sharpless, Klostermann, & McCarthy, 2007; Simons et al., 2010). The extensive resources and time taken to train these clinicians currently is therefore expensive (currently highly specialised clinicians with post-graduate training in CBT are required). This in turn restricts the number of sufficiently trained clinicians available and thus the public's access to evidence-based

treatments. With further evaluation and refinement of the intervention examined here, tCBT on the other hand has the potential to provide significant savings in terms of the costs and time required to train clinicians. This is because tCBT comprises a distilled set of techniques that can be readily applied to a range of disorders. Therefore, a shift to delivering tCBT would mean clinicians could concentrate on mastering a simpler, more stream-lined set of techniques to a high standard and could enable more junior clinicians (such as Psychological Wellbeing Practitioners; PWPs) to deliver these treatments too. For instance, if the efficacy of tCBT treatments is established in future research and treatment guidelines, low intensity versions of the intervention for mild to moderate cases of comorbidity (e.g. guided self-help materials and group-based interventions) could be designed to be delivered by PWPs. The ability to train more therapists, and together with the time-saved delivering a single vs. multiple disorder-specific protocol, would create much needed improvements in access to effective psychological interventions, especially for older people. These time and cost savings could also help mental health services such as IAPT to move closer to the 12% representation target of older people (from 4%) set out in the 'Talking Therapies: four year plan of action' (DoH, 2011).

The parsimony of tCBT also represents an advantage to older people. For instance, tCBT has the potential to simplify treatment planning for older people with comorbid disorders (as comorbid symptoms can be addressed with a single rather than multiple protocols). tCBT also provides a more distilled and generalisable set of core therapeutic techniques for older people to acquire. Research demonstrates that the ability to attain and analyse new information declines with age ('Fluid intelligence' [G*f*]; O'Brien, 1999), therefore a reduction in the number of new techniques presented could facilitate skill acquisition in older people. The time saved learning new skills would allow older people more time to focus on embedding these skills in to their every day lives, which could benefit the durability of treatment gains.

Furthermore, because the core skills presented in tCBT are applicable across mood disorders (e.g. rather than for a specific anxiety disorder), older people may be more equipped to implement the same techniques to new difficulties arising in the future. This could help to prevent relapse and therefore the need to re-access services, or where a re-referral was required psychological intervention could focus on briefly refreshing previously learned principles, rather than introducing new ones.

5.2.2 Implications for the future refinement of tCBT for older people

This initial adaptation and application of the UP (Barlow et al., 2011) to an older, British audience would benefit from further refinement and evaluation to enhance its efficacy, feasibility and acceptability. On reflecting on the delivery of the UP with this older age group the study therapists identified several potential targets for future modification, which are in line with recommendations arising from the older adult literature. Table 22 summarises the session-by-session UP protocol delivered in the current study and contrasts this against the suggested future adaptations, which are considered in turn below.

Experiential exercises vs. cognitive restructuring

An important future adaptation to the current protocol would be to create a greater emphasis on behavioural content and experiential exercises earlier on in treatment. This would enable the early identification and remedy of any barriers to completing exposure exercises, and provide multi-sensory experiences and the opportunity to learn through action, which is known to be more powerful than didactic instruction alone and particularly useful when working with older people (Evans, 2007). Therefore, a greater emphasis on behavioural exercises might benefit the acquisition of new skills in this population and provide live access to thoughts and fears (for the purpose of thought challenging), which an older person may struggle to imagine and manipulate out of context.

As Table 15 illustrates, in practice this might involve moving sessions 8, 10 and 11 (addressing emotional avoidance and facing feared situations) from the end of treatment to the first half of treatment (session 1-6). This could then follow with the introduction and use of mindfulness techniques (currently session 4-5) to aid patients continued progression through their graded exposure exercises. A greater emphasis on mindfulness techniques could also provide a more feasible alternative to cognitive restructuring, which was consistently difficult to implement in the current study. As discussed earlier research also suggests that older people can struggle to acquire this skill (Opitz et al., 2012; Chand & Gossberg, 2013), and it may not be necessary to alleviate mood symptoms (Jacobson et al., 1996; Hayes, 2004; Borkovec et al., 2002). A shift to developing a greater awareness of maladaptive cognitions rather than challenging them may be less confusing to patients and thus more acceptable (as currently both techniques are taught, despite their conflicting ethos). Mindfulness skills might also be more widely beneficial to older people given their utility for other common complaints such as chronic pain (Kabat-Zinn, Lipworth & Burney, 1985) and living with long-term health conditions (Merkes, 2010). It may also be more feasible and efficient to create more time for older people to practice and master mindfulness skills rather than extending the length of the intervention in order to create sufficient time to cover cognitive restructuring techniques.

Additional content:

Another potential adaptation would be to include more content on common age-related issues (e.g. pain management, carer wellbeing, fear of falling). This could perhaps take the form of optional additional modules for specific concerns, which could be selected based on the idiosyncratic presentation of the individual. Table 14 also highlights the suggestion to make the session on 'Confronting physical sensations' an optional module, given feedback that it was not easily applicable to patients with a predominantly depressed presentation.

Moving away from a session-by-session protocol to a set of core modules with a range of optional 'add-on' modules would enable a greater sense of flexibility (which was also called for) and is likely be a more efficient and effective treatment strategy. This shift to a modular rather than session-by-session strategy is also consistent with Ellard et al.'s (2010) aims to enhance opportunities for skill acquisition and promote individualised patient care.

Table 15: Summary of current tCBT protocol contrasted against suggested future adaptations.

Current protocol		**Suggested future protocol**	
Aims	**Content/Skill**	**Session**	**Content/Skill**
'Getting Motivated and Setting Goals for Treatment'	Identify the pros and cons of change and specific treatment goals.	1	Same
'Understanding Emotions'	Examine the 3 components of emotional experience (thoughts, emotions/sensations, behaviours) and begin monitoring these.	2	Same
'Recognising and Tracking Emotional Behaviours'	Identify the triggers and responses to emotional experiences, as well as the short- and long-term consequences of these responses.	3	Same
'Learning to Observe Experiences'	Introduce principles of non-judgmental awareness. Practice a brief mindfulness exercise.	4	Move forward Session 8: 'Understanding behaviours'. Identify patterns of emotional avoidance and maladaptive Emotion Driven Behaviours (EDBs). Begin monitoring these and practicing employing behaviours to counter them.
'Learning to Observe Experiences'	Practice a mood-induction exercise. Practice anchoring in the present moment.	5	Move forward Session 10: 'Facing emotions and feared situations' Create a graded hierarchy of situations and sensations currently avoided and begin confronting these.

'Understanding Thoughts'	Identify negative automatic thoughts (NATs) or 'thinking traps'.	6	<u>Move forward Session 11: 'Facing emotions and feared situations'</u> Continue to confront situations in the hierarchy whilst using the skills learnt during treatment.
'Understanding Thoughts'	Practice generating more balanced alternatives to NATs.	7	<u>Move Session 4: 'Learning to Observe Experiences'</u> Introduce principles of non-judgmental awareness. Practice a brief mindfulness exercise (e.g. '3-minute breathing space') Practice bringing mindful awareness to exposure exercises in graded hierarchy.
'Understanding Behaviours'	Identify patterns of emotional avoidance and maladaptive Emotion Driven Behaviours (EDBs). Begin monitoring these and practicing employing behaviours to counter them.	8	<u>Move Session 5: 'Learning to Observe Experiences'</u> Continue practicing mindfulness techniques (e.g. mindful walking exercise, body scan). Introduce anchoring in the present.
'Understanding and Confronting Physical Sensations'	Conduct interoceptive exposure exercises designed to elicit different physical sensations which mimic problematic mood symptoms.	9	Continue working through graded hierarchy using techniques learnt.
'Facing Emotions and Feared Situations'	Create a graded hierarchy of situations and sensations currently avoided. Systematically confront these situations whilst using the skills learnt during treatment (e.g. present-focused awareness, cognitive reappraisal).	10	Continue working through graded hierarchy/practicing mindful awareness (e.g. of thoughts, sensations) using techniques learnt.

'Facing Emotions and Feared Situations'	Continue to confront situations in the hierarchy whilst using the skills learnt during treatment (e.g. present-focused awareness, cognitive reappraisal).	11	Continue working through graded hierarchy/practicing mindful awareness (e.g. of thoughts, sensations) using techniques learnt.
'Relapse Prevention'	Review key concepts and skills covered during treatment, evaluate treatment progress and set short- and long-term goals for maintaining treatment gains.	12	Same
		Examples of optional Additional Modules	
			'Confronting Physical Sensations'
			'Pain management'
			'Carer wellbeing'
			"Fear of falling'

Materials

Another necessary adaptation would be to substantially reduce the volume of information presented in the materials given to participants and use simpler and more concrete language. Some of the examples and vignettes were highlighted as unhelpful either because they did not adequately represent the lifestyles and concerns of the different subgroups within this population or because the clinical presentation depicted in an example (e.g. panic) was not directly applicable to the client's own concerns (e.g. pain). It is important to take note of the heterogeneity of older people's experiences, lifestyles and attitudes. One potential solution to this challenge is to remove the examples and vignettes from the handouts given to participants (which would reduce the amount of content in line with another suggestion) and for the therapist to create these on an individual basis with each client when introducing new concepts.

Flexibility and familial support

A final proposed adaptation would be to instil a more flexible approach to the delivery of the protocol and enlist greater familial support (where appropriate and possible). For example, it would be beneficial if clinicians could decide how many sessions (e.g. between 1 and 3) to spend on each section of the protocol in order to accommodate different rates of learning and processing speed. A flexible approach to the frequency and location of sessions is also needed, given the particular needs of some older people. For instance, more frequent sessions (bi-weekly, especially at the beginning of treatment) may be helpful to create momentum and provide support with the completion of experiential exercises, which may not be available within the patient's network. Likewise, it can sometimes be necessary (due to frequent medical appointments) and/or preferable (due to a care giving responsibilities) to have sessions arranged over a greater span of time (e.g. bi-monthly) in order to enable sufficient time for the patient to complete homework tasks. It was often more feasible and preferable to participants in the current study to be seen within their own homes, and this held several advantages over seeing participants in an out-patient clinic. It was easier to establish barriers and facilitators to

completing homework tasks and exposure exercises (e.g. creating memory aids within the home). This also provided ready access (where appropriate) to the patient's family network, which enabled clear identification of care giving challenges as well as significant others who could support and facilitate behaviour change. Where family members are not available to support patients with homework tasks it might be beneficial for therapists to conduct brief between-session telephone calls to the patient in order to prompt and coach the patient through homework assignments (Dreer, Copeland & Cheavens, 2011). In addition, therapists could accompany the patient when completing tasks on their graded hierarchy to help build their confidence (e.g. attending a local day-care centre for the first time).

5.3 Methodological issues

Despite the encouraging findings achieved by this study, several methodological issues (e.g. small sample size, reliance on self-report outcome measures, lack of follow-up data, uncontrolled use of concomitant psychotropic medication and the lack of an active placebo control condition) must be considered when evaluating the findings of the current study. The implications of each of these issues are discussed in turn below.

5.3.1 Small sample size

A major limitation of the present study was its small sample size (n=15), which is likely to have provided insufficient statistical power to reliably examine differences between variables, and may account for why significant between-group differences were only found in terms of depression, and not anxiety or general mood symptoms (n=7/8 per group). The HADS depression subscale achieved the largest effect size (d=0.78) of all the outcome measures, and so it is likely that a larger sample size was required to detect between-group differences in anxiety and general mood symptoms. As such it cannot be ruled out that a type II error has resulted here.

It is important to emphasise that a larger sample size was originally planned (n=22), albeit still relatively small. However there were several recruitment issues, which precluded this from being achieved. Firstly, two out of the four boroughs recruited from struggled to identify sufficient numbers of potential referrals due to the greater availability of primary care psychological therapy services, which led to referrals being of a more complex nature and therefore often unsuitable for the study. Moreover, the reliance on CMHTs more generally as the source of study referrals meant that potential participants tended to exceed initial clinical symptom severity cut-offs (this criterion was later removed), and not always be able to safely tolerate a potential 7-week wait for treatment. They also tended to have complex presentations due to comorbid diagnoses that prohibited their participation in the study (e.g. dementia, personality disorder), and/or required a level of flexibility that was not possible to provide in a treatment trial (e.g. they required more sessions to facilitate treatment engagement and tackle treatment interfering behaviours such as emotional instability and intolerance to distress).

A further factor, which impacted on recruitment rates, was the initial requirement for potential participants to stabilise on their psychotropic medication for 8-weeks prior to commencing in the study (this criterion was later removed). Although this criterion initially enhanced the quality of the study, it is common for patients to begin or have alterations made to their medication when they are referred to and assessed by a CMHT. Therefore, this ruled out a large proportion of potential participants. Even for those otherwise suitable and keen to take part, the potential wait posed by an 8-week stabilisation phase, plus a potential 7-week delayed treatment allocation, was often unfeasible and unethical (as a shorter waiting time could be expected if accessing routine psychology services). Due to the negative impact this requirement had on recruitment rates, it was later removed with the support of ethical approval, and benefited subsequent recruitment rates. However, the removal of this requirement does compromise the conclusions that can be drawn from the study findings and is discussed further in section 5.3.4.

5.3.2 Reliance on self-report measures

Another methodological limitation of the current study was its reliance on self-report measures to evaluate changes in symptomology and impairment. The validity and reliability of self-report data can be compromised by various sources of bias such as recall and social-desirability bias, and errors in self-observation. Therefore, it will be important for future research to replicate and corroborate the study findings with independent clinician ratings. Furthermore, evidence from a recent meta-analysis of CBT for depression in older people revealed smaller effect sizes for self- compared to clinician-rated measures (Gould et al., 2012b). This suggests that the reliance on self-report measures may have underestimated the degree of change achieved by the tCBT intervention and clinician-rated measures are also required to ensure a more accurate estimate of change and clinical efficacy. Although clinician-rated measures were used as part of the initial screening assessment (HAM-A and HAM-D), these were not utilised to measure changes in outcome at mid- and post-treatment due to the limited size of the research team and failure to identify suitably experienced independent outcome assessors for this purpose.

In terms of the self-report measures used in the current study (HADS and CORE-10), these were selected partly for their efficacy in measuring symptoms of anxiety and depression in older people (Kenn et al., 1987; Spinhoven et al., 1997; Helvick, Engedel, Scancke, & Selbæk, 2011; Roberts, Fletcher & Merrick, 2014) and partly because these are quick to complete and the key outcome measures utilised by the older adult services within SLaM. The HADS in particular is argued to be particularly suitable for use with older people as it was originally designed for use with physically ill people and to minimise the influence of concomitant physical illnesses on the measurement of mood (Laidlaw et al., 2004). However, it should be highlighted that most of the studies evaluating the validity of the HADS with older people has tended to focus on the depression subscale (Kenn et al., 1987; Spinhoven et al., 1997, Helvick et al., 2011) and there is some evidence to suggest that the HADS is poorer at detecting changes in anxiety symptoms in older adults (Davies et al.,

1993). This could partly explain the smaller rates of 'recovered' and 'reliably improved' found here in terms of anxiety symptoms.

5.3.3 Lack of follow-up data

Another important limitation of the current study is the lack of a follow-up assessment. Consequently, the persistence of the treatment gains noted here is not known and cannot be presumed. It can also not be ruled out that the full extent of treatment gains achieved by the intervention may not be evident until several weeks following treatment when participants have had more opportunity to put their newly acquired skills into practice. It is vital that future evaluations continue to assess participants following the intervention in order to determine whether tCBT can achieve similarly durable outcomes to existing disorder-specific CBT interventions and other evaluations of the UP (see section 5.4 for further discussion on this issue).

5.3.4 Uncontrolled use of concomitant psychotropic medication

The requirement for participants to stabilise on their concomitant psychotropic medication prior to commencing in the study was later withdrawn in order to facilitate recruitment rates. As such, changes in psychotropic medication were not controlled and therefore the extent to which changes (increases and decreases) in pharmacotherapy contributed to symptom improvement and deterioration (as side effects experienced when medication is changed can mimic mood symptoms such as fatigue, shakiness, etc) cannot be clearly established. However, what is known is that participants who were not in receipt of psychotropic medication or did not experience dose changes during the course of the study (n=5) were among those to report improvements in their symptomology, which provides tentative evidence to suggest that the tCBT intervention was responsible for a proportion of the treatment gains.

5.3.5 Lack of an active placebo comparison group

The tCBT intervention was compared to a 7-week delayed-treatment control condition and not an active placebo intervention that controlled for non-specific therapeutic factors (such as perceiving your therapist to be empathic and competent), which can affect treatment outcome (Chatoor & Krupnick, 2001). Therefore, the extent to which the distinct components of tCBT contributed to symptom reduction is unknown.

5.3.6 Treatment adherence checklist

The measure used to assess treatment adherence (see appendix 11) was not validated and therefore its reliability and validity is untested, and its ability to consistently and accurately capture adherence to the UP may have been compromised. Also, whilst the checklist assessed therapist adherence it did not assess therapist competence, which is another key component of treatment fidelity associated with outcome (Waltz, Addis, Koerner & Jacobson, 1993).

To assess therapist competence, the rater requires a thorough grounding in the therapeutic model and intervention under scrutiny in order to accurately judge the skill of the therapist and the appropriateness and timing of interventions used (Stiles, Honos-Webb, & Surko, 1998). Unfortunately it was not possible to identify a suitably experienced, independent clinician for this purpose. It is also not clear which form of therapist competence measure it would have been appropriate to employ as neither adherence or competence has yet been formally examined in the Barlow group trials of the UP (Ellard et al., 2010; Farchione et al., 2013). The Cognitive Therapy Scale-Revised (Blackburn, James, Milne & Reichelt, 2001) could potentially have been employed, however this is time-consuming to complete, and was designed to assess traditional disorder-specific CBT interventions, and therefore its ability to reliably and accurately assess tCBT interventions is unknown and untested.

5.3.7 RCT design

Whilst a RCT provides a robust, 'gold-standard' design to evaluate efficacy due to its ability to control for and balance factors that may affect outcome, its artificiality limits its external validity and the ability to generalise findings to real-world clinical settings. It could be questioned with regard to the 'hourglass model' of treatment development (Salkovskis, 1995) why such a stringent research design was adopted given that this was a novel pilot study. The hourglass model posits that highly controlled studies are relevant for only one portion of the development cycle (neck of the hourglass), while less controlled methods (such as case studies and effectiveness studies) are more appropriate during the early and late stages. However, whilst this was a pilot study of an intervention conducted with a novel population, the theoretical basis of the UP (CBT) has been extensively studied and CBT is recognised as an effective evidence-based treatment for older people (Gould et al., 2012a, Gould et al., 2012b). Therefore, a RCT design was chosen over arguably more clinically sensitive and tentative methodologies (e.g. case series, which are subject to several biases) based on the strength of the existing CBT evidence base, but also in order to provide a robust evaluation of the intervention and enable confident conclusions to be drawn regarding its efficacy. The RCT design utilised was arguably clinically sensitive given that significant between-group differences were found despite an underpowered sample size and after only half the intervention had been delivered. As a result the preliminary efficacy estimates gained here will be able to inform the future refinement of the UP and add weight to the application for funds to conduct a larger scale trial with this population.

5.3.8 Study therapists

It is important to acknowledge that one of the study therapists was also the chief investigator, as this arrangement may have given rise to different forms of bias. Researcher allegiance, which is a researcher's belief in the superiority of a treatment and/or the theory of change associated with a treatment is one form of potential bias here and has

been shown to be positively associated with treatment outcome (Munder et al., 2013). Strong researcher allegiance can affect the way participants are treated/assessed, the way the intervention is delivered or data is recorded. In the current study however, safeguards including monthly supervision and treatment adherence monitoring helped to minimise the potential risk of this bias. Social desirability bias (answering questions in a manner that will be viewed favourably) may also have come in to play here as approximately half of the participants completed their weekly self-report measures in the presence of the chief investigator. The risk of this bias was minimised by emphasising to participants that there was no right or wrong answer and encouraging them to answer the questions independently and honestly. This risk could be further minimised by the additional collection of clinician-rated measures throughout the intervention in future trials of this intervention.

5.4 Future research

Future research should seek to further improve the efficacy of this adapted protocol for older people with emotional disorders, by looking to incorporate the modifications discussed in section 5.2.2, and evaluating this revised tCBT protocol with a larger sample, powered to detect between-group differences. Encouragingly, targeted modification of an initial version of the UP for working-age people led to increased rates of recovery and maintenance of treatment gains (Ellard et al., 2010). In accordance with the methodological limitations of the pilot study, future evaluations of tCBT with this population should seek to incorporate a longer delayed-treatment phase (in order to allow between group differences in mood symptoms to be analysed at the post-treatment point) and prioritise the additional collection of clinician-rated measures of mood (e.g. the HAM-A &-D), occupation/function (e.g. the Social Functioning Questionnaire; Tyrer, 1990) and impairment (e.g. Euroqol32 to measure health-related quality of life; Brooks, 1996). Participants should be required to stabilise on their current dose of psychotropic medication for a minimum of 8-weeks prior to commencing in the trial, and follow-up data would ideally be collected at 3-, 6- and 12-months following the intervention in order to establish the durability of treatment

gains. Research comparing tCBT with an active placebo condition that specifically controls for potential non-specific therapeutic factors (e.g. a talking control condition such as that used by Serfaty et al., 2009) is also needed in order to determine whether the distinct components of the tCBT intervention are uniquely responsible for the promising indications of efficacy noted here. In addition, further research comparing tCBT with other disorder-specific CBT protocols is required in order to evaluate possible benefits of adopting transdiagnostic approaches such as greater cost effectiveness.

5.5 Conclusions

Overall this study meets a need to develop efficacious, feasible and acceptable transdiagnostic interventions to tackle the problem of comorbid anxiety and depression in older people. Tackling both disorders at once is likely to be time and cost-effective and produce superior outcomes to treatments that take a disorder-specific approach. This study has demonstrated that tCBT can produce efficacious outcomes for older people with comorbid emotional disorders and that it is both feasible and acceptable to apply tCBT interventions to this population. The results and experiences of this initial application of an established tCBT intervention to an older audience are encouraging and hold several clinical implications for the continued development and improvement of evidence-based psychological treatments for older people.

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A pilot randomised controlled trial examining the feasibility, acceptability and efficacy of transdiagnostic CBT for depression and anxiety in older people.

Primary supervisor: Dr. Rebecca Gould
Second supervisor: Dr Patrick McGuinness

Aims:

This study will aim to evaluate the feasibility, acceptability and efficacy of individual transdiagnostic CBT (tCBT) versus delayed-treatment for depression and anxiety in older people.

Objectives

- To examine whether it is feasible to establish a tCBT intervention for older people with depression and anxiety (including whether it is feasible to adapt tCBT for older, British people).
- To assess the acceptability of tCBT for depression and anxiety in older people.
- To determine preliminary estimates of the efficacy of tCBT for reducing current symptoms of depression and anxiety in older people.

Background:

Anxiety and mood disorders are common in older people and frequently co-occur. A large community study examining over 3000 55-85 year-olds revealed that almost half (47.5%) of those with a major-depressive disorder also met criteria for an anxiety disorder, while approximately a quarter (26.1%) with an anxiety disorder also met criteria for a depressive disorder (Beekman et al., 2000). Cognitive Behavioural Therapy (CBT) is one of the recommended psychological interventions for targeting these conditions in working-age people (NICE, 2007, 2009). Recent meta-analyses have confirmed that CBT is effective in alleviating these conditions in older people (e.g. Wilson, Mottram & Vassilas, 2008; Gould, Coulson & Howard, 2012; Gould, Coulson & Howard, in press). However, reports also suggest that many older people experience difficulty accessing psychological therapies (Ghosh, 2009). There are several reasons why this may be the case, one being the proliferation of disorder-specific CBT manuals. Until recently, researchers have focussed on identifying the constructs that are distinct and specific to separate psychological disorders. This attention has been fruitful in furthering our understanding of the defining features and mechanisms of specific disorders. However, this has resulted in the development of an array of disorder-specific treatment protocols, which has led to inefficiency in training (since this is required for each protocol) and treatment administration (since multiple treatment protocols may need to be applied to a client presenting with comorbid psychological disorders [Clark, 2009]). This emphasis on disorder-specific protocols has substantially hindered the dissemination of evidence-based treatments and thus the public's access to them (McHugh & Barlow, 2010).

The shortcomings of disorder-specific CBT protocols have led researchers to develop more parsimonious CBT-based treatments. One such treatment is transdiagnostic CBT (tCBT), which is an emerging approach to the treatment of comorbid psychological disorders (Barlow et al., 2011). It was developed following growing evidence of considerable overlap between emotional disorders (e.g. Mansell, Harvey, Watkins & Shafran, 2008). One of the foremost indicators of this overlap is represented in the high degree of comorbidity amongst these

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disorders, as noted above. Another strong indicator lies in the apparent lack of treatment specificity resulting from disorder-specific manuals. For example, CBT targeting one anxiety disorder (e.g. panic) has been shown to reduce other comorbid anxiety disorders and depression (Tsao, Mystkowski, Zucker & Craske, 2002), a finding that has been replicated in a meta-analysis of CBT for anxiety disorders in older people (Gould et al., 2012).

There is also mounting evidence indicating the presence of several shared cognitive (e.g. attention, memory and thought) and behavioural processes, which have been hypothesised to maintain a range of emotional disorders. With respect to cognitive processes, studies using the dot-probe task have found consistently shorter reaction times when participants are presented with threat-related stimuli relative to neutral stimuli (Bar-Haim et al., 2007). Likewise, individuals with a range of affective disorders reliably demonstrate a Stroop effect for words that relate to their concerns (e.g. Depression: Gotlib & Cane, 1997; Generalised Anxiety Disorder: Mathews & MacLeod, 1985). There is research indicating that intrusive memories (Holmes & Hackmann, 2004), thought suppression (Purdon, 1999), and recurrent negative thinking (Ehring & Watkins, 2008) are similarly elevated across the emotional disorders. Furthermore, structural equation modelling of the factor structure of emotional disorders has revealed shared higher-order factors (negative affect and low positive affect), implying there may be a common underlying vulnerability to these disorders (Brown, Chorpita & Barlow, 1998). In terms of behavioural processes, Harvey, Watkins, Mansell and Shafran (2004) propose that avoidance (e.g. of negative affect or threat-stimuli) and safety-seeking behaviours are evident across emotional disorders. It is argued that they work similarly to limit opportunities for positive reinforcement and prevent the disconfirmation of dysfunctional beliefs, thus maintaining the disorders. Overall, this body of research proposes that there are cognitive and behavioural processes that may be 'transdiagnostic', and which support the idea of common rather than distinct psychopathologies in anxiety and depression. These findings suggest that emotional disorders may be better addressed using a single rather than multiple set of therapeutic principles, which target common maintaining processes rather than distinct psychopathologies. Consequently, tCBT may represent a viable solution to this problem, and to the present difficulties in disseminating and accessing psychological therapy.

Several recent randomised controlled trials (RCTs; Norton, 2011; Titov et al., 2011; Johnston et al., 2011) comparing tCBT with waiting-list controls or other psychological interventions (e.g. relaxation training) have revealed beneficial effects of tCBT on depression and anxiety when applied to working-age people. In addition, a meta-analysis and review of transdiagnostic treatments for anxiety disorders and depression has confirmed that these interventions yield similar outcomes to traditional disorder-specific treatments (McEvoy, Nathan & Norton, 2009; Norton & Philipp, 2008). Furthermore, a preliminary RCT has demonstrated treatment equivalence of 12-week tCBT and diagnosis-specific CBT for a range of anxiety disorders (Norton & Barrera, 2012). Support for the efficacy of specific tCBT protocols, namely the Unified Protocol for Transdiagnostic Treatment of Emotional Disorders (UP; Barlow et al., 2011), is also growing. The UP is a manualised version of tCBT, which distils empirically supported CBT techniques and is designed to be applicable to anxiety and unipolar mood disorders. In two open trials of the UP for heterogeneous anxiety and depressive disorders, significant pre-post treatment improvements in anxiety and depression

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symptoms were reported (Ellard et al., 2010; Wilamowska et al., 2010). These initial trials prompted a series of adaptations (e.g. reordering and further emphasis of core treatment concepts), which appears to have resulted in further enhancement of pre-post treatment outcomes. Most recently, Farchione et al. (2012) evaluated the effectiveness of a revised version of the UP in an RCT. Thirty-seven people with a principle anxiety disorder and/or a co-occurring depressive disorder were randomised to receive individual tCBT either immediately or following a 16-week delay. In comparison to those in the waiting-list condition, tCBT resulted in significant improvements in symptoms of anxiety and depression, and these gains were maintained at 6-month follow-up.

In summary, tCBT appears to present a more clinically- and cost-effective solution to alleviating comorbid emotional disorders than traditional disorder-specific methods. It is also likely to enable much needed improvements in the dissemination of and access to evidence-based psychological therapies for older people. However, the potential benefits of this approach have not yet been examined in older people. It is important not to presume its efficacy in older people as their response to tCBT may differ to that of working-age people for numerous reasons (e.g. due to more diverse aetiology and physical comorbidities in older people). Before its efficacy can be established in older people, it is necessary to examine the feasibility and acceptability of tCBT in this population. Preliminary attempts to adapt the acceptability of the UP to a younger audience (Ehrenreich, Goldstein, Wright & Barlow, 2009) have proved useful and encouraging, which is promising for the aims of this proposal. Thus, this study seeks to evaluate the feasibility and acceptability of tCBT for comorbid depression and anxiety in older people. It will also ascertain preliminary estimates of its efficacy in comparison to a delayed-treatment control condition in this population.

Hypotheses:

The main hypotheses are:

i. It will be feasible to adapt and establish a tCBT intervention for older people with comorbid depressive and anxiety disorders.
ii. The tCBT intervention will be acceptable to older people with comorbid depressive and anxiety disorders.
iii. The tCBT intervention will significantly reduce depression and anxiety symptoms relative to a delayed-treatment control condition.

Design:

The design will comprise a pilot RCT with 2 treatment arms. Participants will be randomly allocated to either individual tCBT plus treatment-as-usual (TAU) or 7-week delayed-treatment plus TAU. The latter arm will serve as a control condition in order to enable between-group comparisons. The study will utilise a mixed-factor 2 (treatment condition) x 4 (time) design. Treatment condition will be a between-subjects factor (tCBT vs. delayed-treatment), and time a within-subjects factor (0-weeks vs. 7 weeks vs. 14 weeks vs. 7-week follow-up). The dependent variables will be scores on clinician-and self-rated outcome measures (see below).

Methods:

Participants

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22 older people with a primary diagnosis of mild to severe depression or anxiety, together with clinical symptoms of another mood disorder (e.g. anxiety or depression respectively), or a mixed anxiety and depressive disorder (as outlined in ICD-10; WHO, 1992) will be recruited from the Mental Health for Older Adults and Dementia Clinical Academic Group (MHOA&D CAG) within the South London and Maudsley NHS Trust. A Consultant Old Age Psychiatrist will have made initial diagnoses. These will then be verified using the Structured Clinical Interview for DSM Disorders (SCID; First, Williams, Spitzer and Gibbon, 2007) during the initial screening assessment (outlined below).

In addition to the diagnosis requirements outlined above, to be eligible for participation service users will need to: be aged 60 years and above; be fluent in English and have sufficient literacy skills to cope with the demands of the intervention (e.g. reading handouts, completing questionnaires). Disorder severity will be determined by administering the Hamilton Anxiety Rating Scale (HARS; Hamilton, 1959) and Hamilton Depression Rating Scale (HDRS; Hamilton, 1960). A score between 8 to 14 on the HARS indicates mild anxiety, 15 to 23 moderate, 24 to 30 severe, and 31 or over very severe anxiety. A score between 8 to 13 on the HDRS indicates mild depression, 14 to 18 moderate, 19 to 22 severe, and 23 or more very severe depression. Participants will therefore need to score above 8 on the HARS or the HDRS for their primary diagnosis in order to be eligible for inclusion in the trial.

Exclusion criteria will include: a current diagnosis of PTSD or complicated grief (as there is evidence that these disorders may not be amenable to transdiagnostic treatments; Erickson, Janeck & Tallman, 2009); severe and enduring mental health disorder (e.g. schizophrenia, schizoaffective disorder, bipolar affective disorder); presence of a personality disorder; presence of an intellectual disability or cognitive impairment (e.g. less than 26 on the Mini-Mental State Examination [MMSE]; Folstein, Folstein, & McHugh, 1975); severe sensory impairment that would significantly impair a person's ability to engage in the intervention; neurodegenerative disease (e.g. dementia) or a neurological condition (e.g. stroke, Parkinson's disease, head injury); current alcohol/substance abuse or dependence; current suicidal risk; and receiving concurrent psychotherapy. Concurrent pharmacotherapy will be allowed.

If any potential participant's care coordinator considers the following then the potential participant will not be included in the trial: 1) the potential participant should receive urgent psychological therapy (even if the potential participant is not expressing active suicidal ideation); or 2) the potential participant would not be able to wait 7 weeks for therapy (should they be allocated to the delayed treatment condition), for whatever reason.

Randomisation

Participants will be randomly allocated to receive individual tCBT plus TAU or 7-week delayed treatment plus TAU on an ongoing basis, at the point of recruitment. Randomisation with minimisation will occur in order to ensure equal numbers in each treatment condition (11 per condition). Randomisation will occur using a sequence of computer-generated random numbers. Numbers will then be placed in sequentially numbered, opaque, sealed envelopes, and an independent administrator will manage treatment allocation.

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Setting

The tCBT intervention will be delivered in the community within a community mental health team-based outpatient clinic, or in participants' homes (depending on each participant's level of mobility).

Therapists and outcome assessors

Screening assessments will be completed by Siobhan Commins. The tCBT intervention will be delivered by Siobhan Commins, Dr. Rebecca Gould (primary supervisor) and 2 other clinical psychologists working within the MHOA&D CAG. An independent experienced CBT therapist in the MHOA&D CAG will provide clinical supervision. An honorary assistant psychologist will serve as an outcome assessor who will be blind to treatment allocation. All therapists will be trained in administering Barlow et al.'s (2011) UP via a training DVD produced by this group.

Screening measures

An initial screening assessment will be conducted with each participant in order to assess whether they meet study inclusion criteria and to determine mental health diagnoses. This will last for approximately 90 minutes, and will utilize a screening measure of cognitive function (MMSE), a semi-structured diagnostic measure (SCID), clinician-rated mood measures (HARS and HDRS) and self-rated mood measures (Clinical Outcomes in Routine Evaluation-10 [CORE-10], Connell & Barkham, 2007; and the Hospital Anxiety and Depression Scale [HADS], Zigmond & Snaith, 1983).

Intervention

The manualised intervention will comprise 12 individual, 1-hour sessions based upon Barlow et al.'s (2011) UP. The first 10 sessions will occur on a weekly basis, while sessions 11-12 will occur on a fortnightly basis in order to facilitate the ending of the intervention. This 12-session intervention will therefore span a total of 14 weeks (for an overview of the proposed intervention timeline see Appendix 1). The UP comprises 4 main treatment components: 1) psychoeducation about emotions and behaviour; 2) changing misappraisals about probabilities and consequences of negative experiences; 3) preventing avoidance of negative emotion triggers; and 4) modifying emotion-driven behaviours (e.g. hypervigilance, withdrawal). The intervention will be adapted in order to account for a UK audience (as the manual was developed in the US) and older people (as the manual was developed for working-age people). The involvement of 1-2 service users will be sought in order to facilitate the adaptation of the tCBT manual for a UK, older audience. Each tCBT session will be audio recorded, and then a random selection reviewed by the clinical supervisor in order to monitor adherence to the manual.

Participants randomised to the delayed-treatment arm will receive a brief telephone call and complete the HADS in order to monitor risk and symptom deterioration during the 7-week delayed treatment phase (see below for what will happen if significant risk arises). They will also receive TAU (e.g. CMHT appointments, case reviews, etc) during this time. At the end of 7 weeks, participants in the delayed-treatment arm will crossover into the treatment arm and receive the tCBT intervention.

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Outcome measures and assessment intervals

The effectiveness of the tCBT intervention will be examined using the HADS/CORE-10 (self-rated measures) and the HARS/HDRS (clinician-rated measures). Both clinician- and self-rated mood measures will be utilised as a recent meta-analysis of CBT for depression revealed smaller effect sizes for self- compared to clinician-rated measures (Gould et al., in press). It may be that smaller changes in self-rated measures are mediated by residual depressive symptoms, and therefore clinician-rated measures may provide a more accurate estimate of change. Therefore, it will be important to include both measures in order to accurately evaluate clinical outcome.

Table 1: Assessment intervals during the intervention and follow-up period for the tCBT and delayed-treatment groups.

Group	**0-weeks**	**7-weeks**	**14-weeks**	**21-weeks**	**28-weeks**
tCBT	PRE	MID	POST	FOLLOW-UP	-
Delayed-treatment	-	PRE	MID	POST	FOLLOW-UP

Table 1 illustrates the assessment intervals during the intervention and follow-up period for the tCBT and delayed-treatment groups. Outcome measures will aim to be completed within 1 week (before or after) of the mid- (week 7/14) and post-intervention points (week 14/21), and within 2 weeks (before or after) the 7-week follow-up point (week 21/28).

The primary outcome measures will be the HADS, HARS and HDRS. The HADS will be completed on a weekly basis throughout the intervention period and once again at 7-week follow-up. The HARS and HDRS will be completed at pre-intervention, mid-intervention, post-intervention, and 7-week follow-up. Once participants in the delayed-treatment arm crossover into the treatment arm they will be evaluated as per the intervention condition. Following entry into the study, an independent outcome assessor who will be blinded to treatment allocation will complete the HARS and HDRS. As is the case with RCTs of psychological therapy, it will not be possible to blind participants and therapists to treatment allocation.

The secondary outcome measures will be the CORE-10 and a Discharge Satisfaction Questionnaire. The CORE-10 will be completed at pre-intervention, mid-intervention, post-intervention, and 7-week follow-up. The Discharge Satisfaction Questionnaire, (developed for the Psychology and Psychological Therapies Service within the MHOA&D CAG) will be completed at post-intervention and used to evaluate the acceptability of the tCBT intervention. This questionnaire assesses satisfaction with therapy using both quantitative and qualitative items (i.e. closed and open-ended questions). Acceptability will also be evaluated based on attrition rates due to dissatisfaction with the intervention. The feasibility of the tCBT intervention will be assessed based on attrition rates due to practical reasons (e.g. difficulty in attending due to mobility issues or physical health problems, etc) and clinician-rated judgments of the intervention (e.g. ease of delivery, etc).

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Sample size

In total, 22 older people with depression and anxiety will be recruited (11 per treatment condition), which will be sufficient to provide estimates of feasibility and acceptability of tCBT. In order to estimate the sample size required to gain preliminary estimates of the efficacy of tCBT, an a priori power analysis was conducted using Hedge's G effect sizes reported in Farchione et al's (2012) recent evaluation of the UP with working-age people. Farchione et al. (2012) reported effect sizes of 1.11 for one depression outcome measure and 1.10 for an anxiety outcome measure (based on between-group differences in post-treatment scores). Therefore, based on the between-group effect sizes of 1.11 and 1.10, a sample size of 22 will be sufficient to yield statistical power of 80% at an alpha level of 0.05. Thus, the proposed sample size will be sufficient to provide preliminary estimates of the efficacy of tCBT in comparison to 7-week delayed treatment. Based on advice from MHOA&D therapists, it is anticipated that attrition rates will be low for individual tCBT as it will be flexible with respect to location of its delivery. With an estimated attrition rate of 18% (4 participants in total), a sample size of 18 would still be sufficient to yield statistical power of 72% (for between-group analyses) and >95% (for within-group analyses) at an alpha level of 0.05.

Data analyses

Both intention-to-treat and completer analyses will be conducted. This study will aim to continually assess any participants who drop-out at the intervals outlined above (see Table 1). However, where this is not possible, the imputation method of 'last observation carried forward' will be used.

Initially, data will be analysed using mixed 2 x 2 analyses of variance (ANOVAs), with treatment condition as a between-subjects independent variable (tCBT vs. delayed-treatment) and time as a within-subjects independent variable (0-weeks vs. 7 weeks; 7-week follow-up will not be included in the mixed ANOVA as crossover of the delayed-treatment group into the treatment group will occur after 7 weeks). The dependent variables will be the change in scores on the clinician-and self-rated outcome measures (HADS, HDRS, HARS, CORE-10), and ratings on the Discharge Satisfaction Questionnaire. Post-hoc pairwise comparisons, adjusted for multiple comparisons, will be conducted to explore statistically significant main effects and interaction terms ($p < 0.05$).

Independent groups *t*-tests will be used to examine any between-group differences in baseline characteristics (e.g. age, sex, symptom severity, years of education, MMSE, etc). If statistically significant differences are found, then these variables will be included as covariates in subsequent analyses (using analyses of covariance [ANCOVA]). Analyses that combine data from participants who have crossed over into the treatment condition with the original treatment condition will also be conducted. An ANCOVA will be employed to co-vary out the effect of waiting time between randomisation and receiving the intervention (as half of the participants will have waited 7 weeks prior to starting the tCBT intervention). Thus, one-way ANCOVAs, with time as a within-subjects variable (0-weeks vs. 7 weeks vs. 14 weeks vs. 7-week follow-up) and initial treatment allocation as a covariate (tCBT vs. 7-week delayed treatment), will be used to examine differences in scores at pre-intervention, mid-intervention, post-intervention and 7-week follow-up in the tCBT condition. Finally, non-parametric tests will be employed if drop-out rates exclude the possibility of analysing data

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using parametric tests. Qualitative content analysis will be used to explore common themes in participants' responses to open-ended questions on the Discharge Satisfaction Questionnaire.

Costs:
Below is a breakdown of the anticipated costs for the project:

Item	Cost
Stationary	£70
Postage (9 x 2nd class stamps per person) = £4.50 x 22	£99
Photocopying	£60
Participant honorarium £20 x 22 participants	£440
Oxford Cognitive Therapy Centre workshop 'Enabling flexible control using transdiagnostic CBT' Location: Warneford Hospital, Oxford Date: Thurs 5th July 2012 Presenter: Dr Warren Mansell *Travel*	£125 £60
	TOTAL = £854

Ethical considerations:
All potential participants will have the opportunity to discuss the study, ask questions and request further information before providing verbal and written informed consent. It will be made clear to participants that they will be free to withdraw from the study at any time. It will also be emphasised that a decision not to participate will in no way affect their existing or future NHS treatment.

Consent forms will be used to obtain permission to audio record the tCBT sessions. All audio recordings will be kept in a locked cabinet and will only be reviewed by the tCBT therapists and clinical supervisor. Participants will be assigned a numerical id number in order to ensure the confidentiality of questionnaires and data. Details of id allocation will be documented in an electronic password-protected document.

Participants will remain under the care of their GP/consultant psychiatrist/care coordinator for the duration of the study. However, they will be monitored weekly with subjective outcome measures that will assess suicide risk and deterioration in anxiety and depression symptoms. If suicidal ideation without intent is expressed at any point in the study then the participant's GP/consultant psychiatrist/care coordinator will be contacted and the participant will continue to be monitored weekly. If suicidal ideation with intent is expressed at any point in the study then the participant's GP/consultant psychiatrist/care coordinator

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will be contacted, and the participant will be withdrawn from the study and referred for urgent psychiatric assessment.

If a participant remains moderately to severely depressed or anxious (as indicated by a score of 19-22 on the HDRS or a score of 25-30 on the HARS) at post-treatment or 7-week follow-up then the participant's GP/consultant psychiatrist/care coordinator will be contacted, and the participant will be withdrawn from the study and referred for individual psychological therapy.

Timeline:

It is anticipated that the project will run to the following timeline:

- March 2012 – submit CAG approval application (completed and approved);
- May 2012 – submit research proposal;
- July 2012 – submit IRAS ethics form;
- August-September 2012 – make adaptations to Barlow et al.'s (2011) therapy manual;
- October-November 2012 – service user involvement and start of recruitment;
- November 2012-June 2013 – deliver tCBT intervention;
- April-August 2013 – collect 7-week follow-up data;
- September 2013–May 2014 - data analyses and write-up;
- May 2014 – submit thesis.

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Appendix 2: CONSORT checklist

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	4
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	14
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	16-59
	2b	Specific objectives or hypotheses	60-61
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	62,32
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	65
Participants	4a	Eligibility criteria for participants	64
	4b	Settings and locations where the data were collected	74
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	66-71, 73-74
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	67
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size	7a	How sample size was determined	65
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	64
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	63
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	63
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	64
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	-

CONSORT 2010 checklist *Page*

Appendix 2: CONSORT checklist

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	75-77
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	75-77
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	78, 81
	13b	For each group, losses and exclusions after randomisation, together with reasons	78,81
Recruitment	14a	Dates defining the periods of recruitment and follow-up	-
	14b	Why the trial ended or was stopped	-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	82-83
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	78, 81
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	84-85
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	-
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	86, 88
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	88
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	125-129
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	116-125
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	108-116
Other information			
Registration	23	Registration number and name of trial registry	62
Protocol	24	Where the full trial protocol can be accessed, if available	62
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	-

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Appendix 3: Ethical approval letter

NHS
Health Research Authority
NRES Committee London - Bromley
Bristol Research Ethics Committee Centre
Whitefriars
Level 3, Block B
Lewins Mead
Bristol
BS1 2NT

Telephone: 0117 342 1387
Facsimile: 0117 342 0445

15 October 2012

Miss Siobhan Commins
Trainee Clinical Psychologist
Institute of Psychiatry, Kings College London
Addiction Sciences Building, Institute of Psychiatry
4 Windsor Walk
London
SE5 8AF

Dear Miss Commins

Study title: **A Pilot Randomised Controlled Trial Examining The Feasibility, Acceptability And Efficacy Of transdiagnostic Cognitive Behaviour Therapy (tCBT) For Depression And Anxiety In Older People.**

REC reference: **12/LO/1462**

Thank you for your letter of 08 October 2012, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Appendix 3: Ethical approval letter

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering Letter		16 August 2012
Evidence of insurance or indemnity		
GP/Consultant Information Sheets	1	13 July 2012
Investigator CV		13 August 2012
Letter of invitation to participant	1	13 July 2012
Other: CV - Academic Supervisor		13 July 2012
Other: CV - Members of the research team		17 August 2012
Other: Information Sheet on Cognitive Behavioural Therapy		
Participant Consent Form	2	08 October 2012
Participant Information Sheet	2	08 October 2012
Protocol	2	15 July 2012
Questionnaire: HADS (Hospital Anxiety & Depression Scale		
Questionnaire: HARS (Hamilton Anxiety Rating Scale)		
Questionnaire: HDRS (Hospital Depression Rating Scale)		
Questionnaire: CORE-10 (Clinical Outcomes of Routine Evaluation -10)		
Questionnaire: Discharge Satisfaction Questionnaire		
REC application		17 August 2012
Referees or other scientific critique report		
Response to Request for Further Information		08 October 2012

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

Appendix 3: Ethical approval letter

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

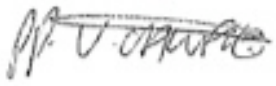
You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

12/LO/1462	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely



Ms Carol Jones
Chair

Email: ubh-tr.BromleyREC@nhs.net

Enclosures: "After ethical review – guidance for researchers" *[SL-AR2]*

Copy to: *Ms Jennifer Liebscher, South London And Maudsley NHS Foundation Trust*

Appendix 4: Consent form

South London and Maudsley NHS
NHS Foundation Trust

Institute of Psychiatry
at the Maudsley

KING'S College LONDON
University of London

Consent Form for Participants *Version 2 (8th Oct 2012)*

An evaluation of the feasibility, acceptability and efficacy of transdiagnostic CBT for the treatment of depression and anxiety in older people.

	Please initial the boxes
I have read the Information Sheet dated 8th Oct 2012 (Version 2) for the above study. I have been given a copy of the document to keep.	☐
I have had the opportunity to consider the information and ask questions about the above study.	☐
I understand that my GP will be informed of my participation in this study.	☐
I understand that my GP/Care Coordinator will be contacted if I express an intention to harm myself or another person.	☐
I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without having to give a reason, and without my NHS treatment or legal rights being affected.	☐
I understand that all of my tCBT sessions will be audio recorded.	☐
I agree to take part in the above study.	☐

Name of participant .....
(IN CAPITALS)

Participant's signature ..... Date: .....

The researcher has explained the study to the participant and has answered the participant's questions honestly and fully.

Name of researcher .....
(IN CAPITALS)

Researcher's signature ..... Date: .....

Thank you for helping with this research

Appendix 5: Information sheet

Institute of Psychiatry headed paper

Participant Information Sheet *Version 1 (13th Jul 2012)*

An evaluation of the feasibility, acceptability and efficacy of transdiagnostic CBT for the treatment of depression and anxiety in older people.

You are being invited to take part in a research study that is being completed in partial fulfilment of a Doctorate in Clinical Psychology. Before you make a decision, it is important for you to understand why the research is being carried out, and what it will involve. Please take time to read the following information carefully and discuss it with your partner, relatives or friends, if you wish. Take time to decide whether or not you wish to take part in the study. Please contact us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?
We are interested in evaluating the use of transdiagnostic Cognitive Behavioural Therapy (tCBT) as a psychological treatment for older people with symptoms of depression and anxiety. In particular, we are interested in evaluating how effective tCBT is in alleviating symptoms of depression and anxiety in older people, how favourably tCBT is perceived by older people, and how feasible it is to adapt and deliver a tCBT intervention to older people living in the UK. Several studies have found tCBT to be helpful and effective in alleviating mood difficulties like depression and anxiety, however this type of treatment has not yet been carefully evaluated with older people with these difficulties. We hope that the results of this study will help us to continue to improve and make available effective psychological treatments for older people with depression and anxiety.

Why have I been chosen?
We are asking 22 people with symptoms of depression and anxiety to take part in this study. You have been approached because you have expressed an interest in the study.

Do I have to take part?
No, it is up to you to decide whether or not you want to take part. If you do decide to take part, then you will be given this information sheet to keep. You will also be asked to sign a consent form and given a copy of this. If you decide to take part, you are free to withdraw from the study at any time, without having to give a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your future NHS treatment or legal rights.

Appendix 5: Information sheet

What will happen to me if I take part?
You will be randomly assigned to one of two conditions. In both cases you will be assigned a treatment therapist who will meet with you on your own for 12, 1-hour tCBT sessions on a weekly basis. If you are allocated to the 'delayed treatment' group though, then this means you will be asked to wait for 7 weeks before beginning the tCBT treatment. Whilst you are waiting to receive the treatment you will receive a brief weekly phone-call from a member of the research team, who will ask you a few questions about your current mood in order to check whether there have been any important changes.

When your tCBT treatment begins you will work with your therapist to develop an understanding of your mood difficulties. You will learn about different techniques that have been shown to help improve mood and wellbeing, and you will be encouraged to experiment applying these techniques in real-life. An important part of the treatment will be practicing these new techniques between your sessions in order to help you make long-lasting improvements to your mood.

In order for us to monitor your mood you will be asked to complete a short questionnaire each week during your treatment. In order for us to assess how beneficial the tCBT treatment is you will be asked to complete some additional questionnaires on 4 occasions: before your treatment starts, half-way through treatment, at the end of treatment, and 7-weeks after your treatment. Some of these questionnaires you will complete on your own and some will be completed with a member of the research team. It is estimated that each of these 4 assessments will take around 30-45 minutes to complete.

What are the possible disadvantages and risks of taking part?
As is the case with all psychological interventions it cannot be guaranteed that the tCBT treatment will be benefit everyone who receives it. Therefore there is a possibility that your mood may worsen or not significantly improve by the end of treatment. Your mood will be regularly monitored throughout the study so that if your mood deteriorates and you express the intention to harm yourself or end your own life, we can withdraw you from the study and notify your GP so that you can be referred for more support. Similarly, if you continue to experience significant symptoms of depression or anxiety at the end of treatment or when we review you 7-weeks after treatment then you will also be withdrawn from the study and notify your GP so that you can be referred for further psychological treatment.

What are the possible benefits of taking part?
You will have the opportunity to receive a new psychological treatment that has been shown to be helpful in alleviating depression and anxiety and is not yet widely available to people in the UK. We hope that the information we get from this study might help us to develop more ways of helping older people with depression and anxiety in the future.

What if new information becomes available during the study?
Sometimes during the course of a research study new information becomes available which may affect your continued participation in the study. For instance if your mood deteriorates and you express the intention to harm yourself or end your own life, then it will be necessary to withdraw you from the study and contact your GP so that you can be referred for more support.

What if there is a problem?
Although we have no specific complaints procedure for this project, in the unlikely event that you are harmed due to our negligence, you are encouraged to approach us. If you have any concerns about the way you have been approached or treated during the course of this study, then please contact Siobhan Commins, Section of Old Age Psychiatry (Box P070), Institute of Psychiatry, De Crespigny Park, London, SE5 8AF, Tel: 07708691877.

Alternatively you can contact Dr Rebecca Gould, Section of Old Age Psychiatry (Box P070), Institute of Psychiatry, De Crespigny Park, London, SE5 8AF. You can also contact Dr Patrick McGuinness, Psychological Therapies Service, Heavers Farm Resource Centre, 122 Selhurst Road, London SE25 6LL. If you wish to complain formally, then you can do this through the NHS Complaints Procedure (details of which can be obtained from South London and Maudsley NHS Trust).

Will my taking part in this study be kept confidential?
All information collected about you will be kept strictly confidential. All information we collect will only be seen by members of the research team. Any research data collected will be assigned a unique identification number so that you cannot be recognised from your data. All research data will be stored securely.

Will my doctor be informed?
Yes we will write to your GP to inform them of your participation, and again at the end of your treatment to update them regarding the outcome.

What will happen to the results of the research study?
When we have collected all the results for this study we will analyse them, and then publish the results. We will also send you a summary of the research findings. You will not be identified in any publication.

Who has reviewed the study?
This study has been reviewed and given favourable opinion by the South London and Maudsley/Institute of Psychiatry NHS Research Ethics Committee. Miss Siobhan Commins' educational supervisors, Drs Rebecca Gould and Patrick McGuinness, have also reviewed it.

Who can I get independent advice from about participating in the study?
You can get independent advice about participating in the study from South London and Maudsley/Institute of Psychiatry Research and Development Office, Institute of Psychiatry, De Crespigny Park, London, SE5 8AF, Tel: 020 7848 0251.

Who do I contact for further information?
If you have any questions or require any further information about this study, then please contact Miss Siobhan Commins, Section of Old Age Psychiatry (Box P070), Institute of Psychiatry, De Crespigny Park, London, SE5 8AF, Tel: 07708619877.

Thank you for considering taking part in this study

Appendix 7: Discharge Satisfaction Questionnaire (DSQ)

South London and Maudsley NHS
NHS Foundation Trust

Psychology & Psychotherapy Service
Mental Health - Older Adults Directorate
Clinical Academic Group (CAG)
115 Denmark Hill
Maudsley Hospital
LONDON SE5 8AZ

Direct Line: 0203 228 1622

Dear Sir or Madam

Psychology and Psychotherapy Questionnaire

You were recently seen by …….. from the Psychology and Psychotherapy Service. We would be grateful if you could answer some questions about your experience of the service you received. You do not have to complete the questionnaire but the information that you provide will help us consider what we are doing well but also more importantly what improvements we could make to the service. Your responses will be treated confidentially and kept anonymous.

Please fill in the form yourself, or with help from someone who can help you. There are two ways to hand the form back to the Psychology and Psychotherapy service:

1. Hand the form back to your Psychologist/ Psychotherapist in the envelope provided.

2. Send the form back to the Psychology and Psychotherapy service in a stamped addressed envelope (SAE). Your Psychologist/ Psychotherapist can provide you (or had provided you) with an SAE.

If you would like to receive information about how the service has responded in general to the feedback provided from all of our service users to our service then please add your contact details here:

Name:
Address:

Thank you very much for completing the questionnaire. If you have any further questions about this questionnaire or how the information from the questionnaire is analysed, please contact Peggy Knee (Administrator) on 0203 2281622

Appendix 7: Discharge Satisfaction Questionnaire (DSQ)

Psychology and Psychotherapy Questionnaire

Please circle the categories that apply to you.

1. **My therapy was:**

Therapy on own	Group	Couple Therapy	Family Therapy	Other	Not sure

2. **I met with my therapist for:**

Less than a month	0-3 months	3-6 months	6 months and over	Not sure

Please circle the degree to which you agree with the following questions. There is space on the back of this sheet for further comments.

3. **Were you satisfied with the wait time for therapy?**

Not at all										Definitely
0	1	2	3	4	5	6	7	8	9	10

4. **Were you satisfied with the location of your therapy?**

Not at all										Definitely
0	1	2	3	4	5	6	7	8	9	10

5. **Did you feel your therapist treated you with dignity and respect?**

Not at all										Definitely
0	1	2	3	4	5	6	7	8	9	10

6. **Did you feel your therapist understood your experiences?**

Not at all										Definitely
0	1	2	3	4	5	6	7	8	9	10

7. **Did you feel that you had enough time to explore your experiences?**

Not at all										Definitely
0	1	2	3	4	5	6	7	8	9	10

Appendix 7: Discharge Satisfaction Questionnaire (DSQ)

Psychology and Psychotherapy Questionnaire

Please circle the categories that apply to you.

1. **My therapy was:**

Therapy on own	Group	Couple Therapy	Family Therapy	Other	Not sure

2. **I met with my therapist for:**

Less than a month	0-3 months	3-6 months	6 months and over	Not sure

Please circle the degree to which you agree with the following questions. There is space on the back of this sheet for further comments.

3. **Were you satisfied with the wait time for therapy?**

Not at all										Definitely
0	1	2	3	4	5	6	7	8	9	10

4. **Were you satisfied with the location of your therapy?**

Not at all										Definitely
0	1	2	3	4	5	6	7	8	9	10

5. **Did you feel your therapist treated you with dignity and respect?**

Not at all										Definitely
0	1	2	3	4	5	6	7	8	9	10

6. **Did you feel your therapist understood your experiences?**

Not at all										Definitely
0	1	2	3	4	5	6	7	8	9	10

7. **Did you feel that you had enough time to explore your experiences?**

Not at all										Definitely
0	1	2	3	4	5	6	7	8	9	10

Appendix 8: Session summary example

Introducing Transdiagnostic Cognitive Behavioural Therapy

➢ **Who is this type of therapy for?**

This type of therapy is designed to help people suffering from a variety of anxiety and depressive disorders, which all fall into the category of *emotional disorders*. Emotional disorders are characterised by a tendency to experience strong, intense, and/or uncomfortable emotions that seem to "take over" a person's life. These aversive experiences may cause people to change their behaviour or avoid situations in ways that begin to interfere in their lives in important ways.

The problem is, by avoiding these experiences, people's lives may become very limited, and they may find it difficult to go about day-to-day activities like going to the Day Care centre, spending time with friends and family, or just doing something leisurely or enjoyable. In addition, avoiding these intense experiences may be causing people to put off pursuing meaningful goals, miss important events, or change important plans. The difficulty is that these intense, strong, and/or uncomfortable experiences may have become the focus of their existence, and may be preventing them from living the life they want. This may be why people seek treatment in the first place.

To help you begin to think about how your emotional experience might be interfering with your life, it can be helpful to ask yourself the following questions:

- What symptoms do I feel I need help with?
- What feelings or emotions seem to go hand and hand with these symptoms? Fear? Worry? Anxiety? Sadness?
- How are these experiences getting in the way of my life? What are they stopping me from doing or achieving?

Appendix 8: Session summary example

- **Outline of the treatment**

The treatment described here is new as it integrates the most powerful psychological techniques and strategies applicable to all emotional disorders in one type of therapy. This treatment consists of 12 weekly, one-hour sessions. In each session of this treatment, we will introduce you to ideas and strategies that will teach you new skills for managing your emotional experiences.

The table below gives a brief outline of the treatment:

Session	Content
1	Maintaining Motivation and Setting Goals for Treatment
2	Understanding Your Emotions
3	Recognising and Tracking Your Emotional Responses
4-5	Learning to Observe Your Emotions and Your Reactions to Them
6-7	Understanding Thoughts: Thinking the Worst and Overestimating the Risk
8	Understanding Emotional Avoidance and Emotion-driven Behaviours
9	Understanding and Confronting Physical Sensations
10-11	Putting it into Practice: Facing Your Emotions in the Situations in which They Occur
12	Moving on From Here: Recognising Your Accomplishments and Looking to Your Future

We will begin by providing you with a deeper understanding of why we have emotions in the first place, how they are adaptive, and how they become maladaptive. You will learn strategies for becoming more aware of your own experiences, and will learn how your thoughts, feelings, and behaviours can all contribute. You will learn specific strategies that, when put into practice, will help you to change less helpful ways of coping you may have developed over time, and replace these with more helpful ways of managing your experiences.

- **The importance of putting skills into practice in between therapy sessions**

Appendix 8: Session summary example

In addition to attending sessions, you will also need to put aside time between sessions in order to really understand and practice the skills presented in the sessions. The importance of doing the exercises presented in each session cannot be emphasised enough. This is not the kind of treatment where you can sit back, wait and hope for results. The success of this treatment is based largely on the amount of effort you put into it. The best way to get success from this treatment is by not just attending the weekly sessions and learning about the concepts, but practicing them between sessions. The more you practice the skills, the more automatic they become. *Learning comes through doing!*

- **Recording your experiences**

Before each session, you will be asked to complete the Hospital Anxiety and Depression Scale and you will record this on a chart each week. This will provide you and your therapist with an ongoing record of your emotional experiences and progress week by week. As you progress through each session, you will also be introduced to specific forms, which will help you to learn and practice each new skill.

- **Why is recording your experiences important?**

Keeping ongoing records of your experience is a crucial part of the success of this treatment. It will help keep yourself moving forward, especially at times when you might feel frustrated or discouraged. Recording your experiences will help you gain a better understanding of them, which will enable you to feel more in control of your experiences. It will also enable you to learn how what we think, feel, and do can all contribute to emotional experiences like anxiety and depression. Finally, it will allow you to evaluate the success of your attempts to change. When we feel anxious, depressed, or distressed in some way, it is easy to dismiss gains and focus instead on how terrible you feel. Recording your experiences will help you to observe and appreciate any gains you make during therapy rather than dismissing them.

Appendix 9: Therapist session notes example

Session 2: Understanding your emotions

Date of session: _____ **Client ID:** ____

Checklist:

HADS completed? ☐ HADS score_____

Homework completed? ☐ If not, reason given:_____

Session aims:

- To learn about the adaptive nature of emotions, and how emotions function to help us in our daily lives.
- To learn what makes up an emotional experience.
- To begin to recognise what makes up your own emotional experiences.

Session summary:

- Collect HADS:
  - *Record score above, plot on progress record*

- Homework review:
  - *Did they finish the Treatment Goal Setting Worksheet? Did they read through chapter 1?*
  - *If not, discuss what may have stopped them from doing this (e.g. lacked motivation, found overwhelming, forgot; record above).*

- Why focus on emotions?
  - *Symptoms of anxiety and/or depression stem from difficulties coping with uncomfortable or distressing emotions or experiences. E.g. someone with social anxiety may find the intense fear they feel in social interactions or in anticipation to a social event severely limits their ability to lead a full social life. Someone with depression may feel so paralysed by sadness and feelings of worthlessness that they cannot motivate themselves to do much of anything.*
  - *Often people seek treatment specifically to try and get rid of uncomfortable emotions. They want the therapist to "take away" or "stop" the negative emotions or "shut off the switch" to the fear circuit in their brain. However, getting rid of these uncomfortable emotions would not be very helpful or adaptive, as they provide us with a lot of important information.*
  - *The goal of treatment is not to eliminate uncomfortable emotions like fear, anxiety, sadness, or anger, etc, but to help you learn how to better understand and tolerate uncomfortable emotions, to see how your responses to your emotions are driving your symptoms.*

- Why do we have emotions?
  - *Emotions are not necessarily "bad" or "dangerous," although they can sometimes feel that way. They tell us very important things about what is going on in our lives. They help us to navigate our world, and to motivate us to do things that are helpful or useful for our survival.*
  - *Imagine what it would be like if we had no emotions or only "good" emotions. E.g. How would we know if our lives were suddenly in danger without a sense of fear?*
  - *Choose example(s) from the chapter (pages 4 to 7) to discuss and illustrate adaptive nature of negative emotions (Fear, sadness, anxiety, anger).*

Appendix 9: Therapist session notes example

- What is an emotion?
  - *Emotions prompt us to engage in specific behaviours, which we call "emotion-driven behaviours" (EDBs). These are often automatic and adaptive.*
  - *It can be difficult to identify anything useful about your emotional experiences or be able to understand what your emotions are trying to tell you. Every emotional experience can be broken down into three main parts – what we think, what we do, and how we physically feel. By identifying each of these parts of your experience, your emotions can begin to feel a bit less overwhelming.*
  - *Compare the thoughts, sensations and actions, which might occur under different emotional states.*
    ***Thoughts:** Triggered by or linked to our feelings. Compare what thoughts someone might have if anxious/happy/afraid.*
    ***Feelings:** There are bodily sensations linked to different feelings. Compare what bodily sensations someone might have if excited/panicky/angry.*
    ***Behaviours:** We respond to our feelings with actions (EDBs). Compare what someone might do if feeling panicky/angry/embarrassed.*

- Three –component Model of Emotions Sheet
  - *Complete this for a recent situation.*

- Set homework
  - *Complete another Three-component Model of Emotions sheet for a situation, which arises during the week.*
  - *Read Chapter 2 of the Client Workbook.*

Session Notes:

Appendix 10: Treatment adherence checklist example

tCBT Trial Adherence Checklist

Session 2: Understanding your emotions

Date session rated: _____ **Client ID:** _____

Rater's initials: _____

Summary of session aims:

- To learn about the adaptive nature of emotions, and how emotions function to help us in our daily lives.
- To learn what makes up an emotional experience.
- To begin to recognise what makes up their own emotional experiences.

Session checklist:

Review

➢ *Was the HADS completed and discussed/plotted on the progress record?*

Yes☐ Partially☐ No☐ Unclear* ☐ (*e.g. recording did not capture the entire session)

➢ *Did the therapist complete a brief review of the previous week with the client?*

Yes☐ Partially☐ No☐ Unclear ☐

➢ *Did the therapist discuss/review the client's homework?*

Yes☐ Partially☐ No☐ Unclear ☐

Core exercise(s)

➢ *Did the therapist discuss and complete the 3-Component Model of Emotions exercise?*
- (Involved discussing and recording a recent example of an emotional situation that the client experienced).

Yes☐ Partially☐ No☐ Unclear ☐

Homework

➢ *Did the therapist set homework with the client?*
- (This was to complete another 3-Component Model of Emotions Form for a situation that arises during the week and read the handout/chapter for Session 2).

Yes☐ Partially☐ No☐ Unclear ☐

Comments: _____

Service Evaluation Project:

Evaluation of the Use, Impacts and Practitioners' Views of an Evidence-Based Assessment Tool (STABILITY) in a Local Authority Service for Looked After Children.

Supervised by:

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1. Abstract:

Background: Improving the stability of foster care placements is a priority for social services (NICE-SCIE, 2010). Placement instability is known to exacerbate negative outcomes for Looked After Children (LAC) and poses a significant challenge to social workers who are faced with finding new and appropriate placements at short notice. Research has revealed several factors that impede and facilitate placement stability. However, less is known about how social workers can best identify these to assess and promote placement stability. In previous work, the "STABILITY" screening tool was developed to meet this need, with input from local psychologists. This service project sought to audit the use and impact of this evidenced-based tool [e.g. practice improvement] during a 3-month pilot phase, and to explore social workers' perceptions of the tool and its associated training.

Method: N=148 social workers in an inner London local authority LAC service were invited to attend training on how to use the STABILITY screening tool and then encouraged to use the tool in their practice to aid their care planning for LAC. Evaluation involved three phases: (1) assessment of training uptake and satisfaction; (2) a prospective case note audit to examine use and impact of STABILITY in practice; (3) qualitative interviews with social workers to examine contextual factors affecting implementation.

Results: N=52 social workers attended the STABILITY training, of whom 83% completed a training satisfaction questionnaire. The content, delivery, relevance and usefulness of the training were each rated as "very good" or "outstanding" by a majority of respondents. However, whilst most of the social workers that attended the training thought that placement stability was relevant to their practice, this did not lead to them using the STABILITY screening tool. Interviews conducted with N=12 social workers revealed several themes regarding the acceptability ('value', 'validity', 'content'), feasibility and barriers ('burden', 'resistance') to using the screening tool as well as some suggestions to improve its use in the future ('mandated use', 'sharing responsibility', 'reminders'). These themes were conceptualised in a model, which hypothesised how these themes related to each other and influenced outcome.

Conclusions: Implementing new service innovations is a dynamic and evolving process. Research on behaviour change within organisations indicates that successful interventions are those that are continuously improved to better fit the needs of individuals and the services they work within. Interviews with the social workers revealed the barriers to its current use as well as clear suggestions to facilitate its use in the future. These were aligned with research and theory on successful behaviour change and gave rise to six future recommendations, which were fed back to the service. If applied to future intervention strategies, these recommendations are likely to improve the acceptability, feasibility and subsequent utility of the STABILITY screening tool within the CYPS.

2. Introduction:

2.1 Looked after children and risks associated with placement instability

The term 'looked after' refers to those children who are in the care of their local authority either due to a court order or a voluntary arrangement made with the child's parents (DoH, 1989). In 2011 there were approximately 65,520 Looked After children (LAC) in England (DfES, 2011). The majority of Looked After children in England reside in foster care placements (74%) and 37% are aged between 10-15 years. Most LAC will enter the care system having already been exposed to an adverse early environment and a variety of stressors such as neglect, abuse, domestic violence and parental loss (Department of Children, Schools and Families, 2009). These experiences in themselves are associated with negative developmental outcomes, and can lead a young person to fail to achieve 'satisfactory wellbeing in adulthood' (Stein & Munro, 2008). The provision of a foster care placement is intended to help improve long-term outcomes for these vulnerable children and prevent further exposure to and accumulation of negative events. However, it is well documented that if these placements are not stable they may in fact replicate and exacerbate existing difficulties (Ward, 2009; Zima et al, 2000). Research indicates that it is not unusual for LAC to have three placements over the course of a year (DfES, 2006), whilst children in the community move home on average three times over the course of their entire childhood (Moyers & Mason, 1995).

A large body of research has consistently demonstrated that placement instability and recurrent placement moves can increase the likelihood of attachment difficulties (Palmer, 2006), emotional and behaviour problems (Newton, Litrownik & Landsverk, 2000), a poor sense of self-esteem and identity (Unrau, Seita, & Putney, 2008), disrupted education and reduced academic performance (Zima et al, 2000) and increased dependence on physical and mental health services (Rubin et al., 2004). Furthermore, there is evidence to suggest that recurrent placement moves may have a cumulative negative effect, as it is associated with future placement

instability (Webster, Barth & Needell, 2000). Following from this evidence, recent social care policies and practice documents have emphasised the need for social services to prioritise improving the stability of the foster placements they provide (DfES, 2007; NICE-SCIE, 2010).

2.2 Factors related to placement instability

In order to promote placement stability it is important to understand the factors that lead to placement breakdown. The research base broadly indicates that factors related to placement instability can be clustered into three categories, factors relating to the child, the placement/carer and the interactions between these (Berridge & Cleaver, 1987, Rock, Michelson, Thomson & Day, 2013).

2.2.1 Child factors

There is consistent evidence that the likelihood of placement instability is higher when the child is older, or has emotional or behavioural problems (James, 2004; Barber & Delfabbro, 2003). The reasons children come into care is also known to be important, with children removed for reasons of neglect more likely to experience placement breakdown than those removed for sexual abuse (Connell, Katz, Saunders & Tebes, 2006).

2.2.2 Placement and carer factors

Oosterman et al's (2007) meta-analysis revealed that experiencing previous placements was a significant predictor of placement breakdown. They also reported that factors relating to the quality of the caregiving provided might protect against risks of placement breakdown. For instance, children in the care of foster carers who were highly motivated, involved and nurturing, and whose foster families had access to resources and support from relatives, tended to be more stable (Kalland & Sinkkonen, 2001). On the other hand, placements where foster carers are experiencing high levels of strain and stress are associated with higher rates of instability (Farmer, Lipscombe & Moyers, 2005).

The interactions between the child and their carer are also important as a negative or hostile interaction style is likely to exacerbate any emotional or behavioural problems the young person may display. A key factor believed to facilitate this relationship is the matching process between child and foster placement. For instance, there is evidence that too large an age gap between the looked after child and the other children in the foster family can lead to discord and placement instability (Berridge, 1997). Unfortunately though, the matching process is often compromised where there are insufficient foster placements and where new placements need to be identified at short notice.

2.3 Usual practice for LAC in the local authority

The current evaluation is concerned with two practice initiatives that were developed and piloted by an inner-London local authority to improve rates of placement stability. The impetus for this project followed the release of figures, which revealed that a high number of placement moves were occurring for LAC in the borough. The project's aims also echo recommendations from a recent review of social work reform (Munro, 2012), which states that services should be child-centred and intervene early to minimise adverse experiences and improve outcomes for children.

The first Placement Stability Project initiative was the introduction of 'Placement Support Meetings' (PSMs). Previously, the practice had been to hold 'Disruption Meetings', which served as a space for professionals to plan placement moves. As the name suggests these meetings tended to be organised after a crisis had occurred and when placement breakdown was imminent. PSMs were created to replace these and signalled a shift in social work practice from crisis-led action to crisis prevention. PSMs are designed to be called at an earlier stage, when difficulties first emerge in a placement. They aim to stabalise and sustain placements by planning how to support the young person and foster family to avert crises and breakdown. The second Placement Stability Project initiative was the development and introduction of the STABILITY screening tool

and its related training. The idea was that the STABILITY screening tool could be completed initially and the resulting information later used to guide a PSM, if this was required.

2.4 The development of the STABILITY screening tool

Rock et al (2013) built on previous reviews (Pardeck, 1985; Holland, Faulkner & Perez-del-Aguila, 2005; Sellick, 2006; Munro & Hardy, 2007; Oosterman et al., 2007) and completed a systematic review and synthesis of research examining the factors associated with placement instability. The most robust risk factors to emerge from the evidence were older age of children, externalising behaviour, longer total time in care, residential care as first placement setting, separation from siblings, foster care versus kinship care, having multiple social workers, being placed outside of area of origin and poor integration into a foster family. A number of protective factors were also identified including the skills, experience and personal characteristics of foster carers, and being placed with siblings. From this a conceptual framework was developed which aimed to bridge the gap between research and practice and ultimately improve the quality of care and outcomes for Looked After children. CLAMHS (Children Looked After Mental Health Service) commissioned both the Rock et al (2013) review and the development of the STABILITY screening tool development as there was an interest in the role of child mental health in placement stability. In particular a decision was made to look more widely at stability factors to ensure wide applicability in practice. The STABILITY screening tool is described in detail in section 3.3.

2.5 Aims of the evaluation

This service project aims to evaluate the use, impact and perceived utility of the STABILITY screening tool by social workers during an initial 3-month pilot phase. The 11-13 year old LAC cohort was identified in a previous audit of children as being at a higher risk of placement move and so was selected as the target group.

More specifically the project aims to address the following questions:

- What was the uptake of the STABILITY screening tool training among invited social workers?
- Did those who attended the training deem it to be acceptable?
- What were the screening tool's patterns of use?
- To what extent is the screening tool perceived as acceptable and feasible to social workers in the context of other practice strategies (such as PSMs) used to promote placement stability?
- What are the barriers and facilitators to the screening tools use by social workers?

3. Method:

3.1 Evaluation design

A mixed method design was used over three phases:

1. Training evaluation – This involved a cross-sectional, post-evaluation of learning outcomes.
2. Case audit – This involved a prospective case note audit of the use and impact of the screening tool following the training.
3. Key informant interviews – This involved a qualitative evaluation of social workers' views of the screening tool.

Governance approval was obtained from the Head of the Children and Young Peoples' Service (CYPS) prior to the commencement of this service evaluation project.

3.2 Service context

The STABILITY project was conducted in one of the most densely populated and socially deprived inner city boroughs in London. The CYPS in this borough provides foster placements to children who are unable to reside with their biological families, most often for reasons of abuse and neglect. According to the latest national statistics on Looked After children this borough hosts the third largest inner London population of LAC, providing over 500 placements, with the most represented age-group being 10-15 year-olds (Department for Education [DfE]; 2011).

3.3 Service intervention

3.3.1 Description of the STABILITY screening tool

The STABILITY screening tool was developed through a multi-agency collaboration between clinical psychologists, LAC service managers, Independent Reviewing Officers (who participate in the care planning process for each child, and ensure that his/her current wishes and feelings are given full consideration) and frontline social workers. The tool

incorporates a practitioner-completed checklist of empirically supported risk and protective factors. The checklist (appendix 1) is designed to be used in conjunction with a set of structured guidance notes that facilitate reflection on the unique risks and strengths of a placement and to guide assessment and care planning for Looked After Children. The checklist incorporates the risk and protective correlates identified in Rock et al (2013) review and organises them into child, birth family, placement, carer or relationship factors. Each individual correlate is expanded by a question, and can be endorsed as historically and/or currently relevant. For example 'externalising behaviour' is followed by 'Is the child displaying aggression, oppositional behaviour and/or offending?'. A reference number accompanies each item on the checklist so that positively endorsed factors can then be looked up in the guidance notes. The guidance notes (appendix 2) contain a series of further points to consider when reflecting on the impact of each factor. For example the externalising behaviour item goes on to ask whether the child is in a gang, if the behaviour could represent underlying distress or hyperactivity, and whether the foster carer is aware and/or concerned about the behaviour. Each of these is then accompanied by an action point to be implemented, such as making a referral to CLAMHS, calling a PSM, or consulting with a particular team or professional. The interventions suggested are based on NICE/SCIE guidelines for LAC and local best practice protocols and procedures.

3.3.2 STABILITY training

Training on how to use the screening tool was delivered in a 2.5-hour session that was repeated for eight separate cohorts over a 6-week period, prior to the start of the pilot phase. The training sessions were led by a senior Clinical Psychologist and senior social worker, who were involved in development of the tool. The aims of the training session were to:

- Introduce social workers to the STABILITY screening tool,
- Highlight the importance of placement stability and the risk factors associated with placement breakdown,

- Provide an opportunity to practise using the screening tool with a case-study example,
- Outline expectations for when and how the screening tool should be used, documented and subsequently incorporated into care plans for LAC

3.3.3 STABILITY implementation standards

Following training it was expected that LAC social workers would use the STABILITY screening tool to screen for the presence of various risk and protective factors in all their 11-13-year-olds' placements. It was expected that completed checklists would be uploaded on to Framework (a secure electronic records system) and its use then evidenced in the corresponding case notes and discussed in supervision (a plan supported by the Head of Service).

3.4 Participants

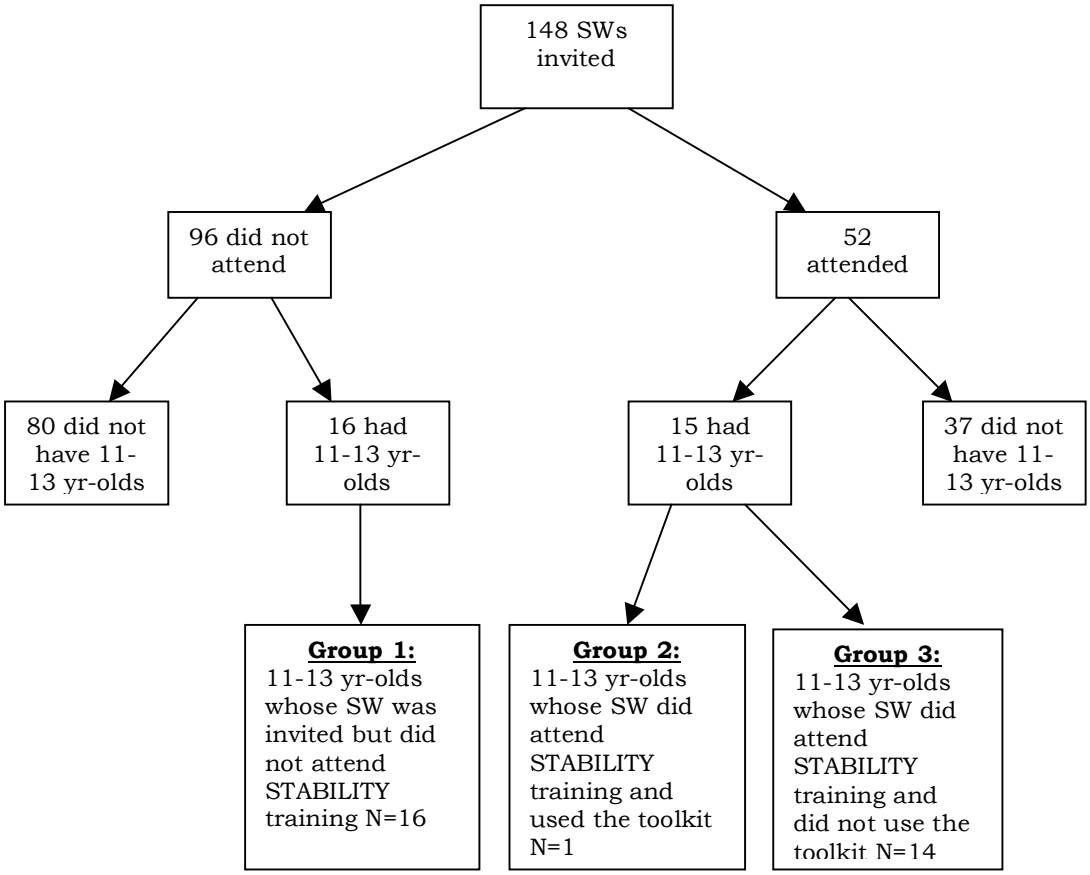
3.4.1 Training

One hundred and forty eight social workers from 15 teams within the CYPS were invited to attend the STABILITY screening tool training (between date January and March 2011). In total, N=52 (35%) attended.

3.4.2 Audit

Seventy-three 11-13-year-olds were in foster care placements during the 3-month pilot phase (1st November 2011 to the 31st January 2012). Of these, 43 were under the care of 15 out of the 52 social workers who attended the training (see figure 1).

Figure 1: Numbers of social workers with 11-13 year-old LAC



Audited cases therefore fell into three groups:

1. Looked After 11-13-year-olds whose social workers were invited, but did not attend the STABILITY screening tool training. This group formed a naturalistic control group from which to draw comparisons with when evaluating the impact of the STABILITY screening tool on practice (n=16).
2. Looked After 11-13-year-olds whose social workers were invited, attended the training and used the STABILITY screening tool (n=1).
3. Looked After 11-13-year-olds whose social workers were invited, attended the training and did not use the STABILITY screening tool (n=14).

3.4.3 Interviews

Twenty social workers were approached for interview at their desk using an opportunistic sampling method. Of these, 12 social workers agreed to

be interviewed (response rate 60%). 6 of the social workers had attended the STABILITY screening tool training and were interviewed individually. A further team of 6 social workers who had not attended the training were interviewed as a group.

3.5 Evaluation measures

3.5.1 Training

The Workforce Development Event Course Evaluation Form (WDECEF) was used to evaluate the STABILITY screening tool training. This measure was developed within the local authority to evaluate in house training (appendix 3). The measure consists of 11 items in total, 8 of which are scored along a 4-point Likert scale (Outstanding - 1, Very Good - 2, Satisfactory - 3, Inadequate - 4) and ask for feedback concerning the objectives, content, relevance, delivery, materials, venue, refreshments and acknowledgement of diversity issues. Lower scores on this measure represent greater satisfaction. The final three items prompt for brief qualitative feedback on the most useful aspects of the course, recommended improvements and how the training will be applied in practice.

3.5.2 Audit

A proforma was created for use when auditing the notes of the target group (appendix 4). This covered the following:

- Social worker identification code (anonymised)
- LAC identification code (anonymised)
- Has use of the STABILITY screening tool been mentioned in the notes? (Yes/No),
- Has it been uploaded on to Framework? (Yes/No),
- Has its use been discussed in supervision and documented on Framework? (Yes/No),
- Has a Placement Support Meeting (PSM) called? (Yes/No),
- Were any placement moves recorded? (Yes/No).

3.5.3 Interviews

A semi-structured topic guide with prompts was created and used when interviewing the social workers (appendix 5). This broadly covered factors affecting their use of the STABILITY Tool; potential links between PSMs and STABILITY; and ideas to facilitate implementation of STABILITY. More specific topics and prompts were developed iteratively in order to reflect and explore emergent themes from the training evaluation, case audit and early interviews.

3.6 Data collection procedures

The data collection was carried out in three phases:

3.6.1 Training

Attendance sheets were completed and the WDECEF was administered at the end of training to evaluate satisfaction.

3.6.2 Audit

The electronic case notes of all 11-13-year-olds LAC in the local authority whose cases were active within the three-month pilot phase (1st November 2011- 31st January 2012) were systematically audited using the proforma.

3.6.3 Interviews

Respondents were informed of the outcomes of the screening tool pilot and then asked questions that explored all topics set out in the pre-defined topic list (appendix 4). Prompts and follow-up questions were responsive to issues emerging from respondents' accounts. Detailed notes of the responses given during the interviews were made.

3.7 Analysis plan

The data collected from each phase were analysed by the following methods.

3.7.1 Training

The quantitative findings from items 1-8 on the WDECEF were analysed using descriptive statistics (mean, median and standard deviation) and triangulated with the qualitative feedback from items 9-11 which was synthesised using content analysis and frequency counts of common themes.

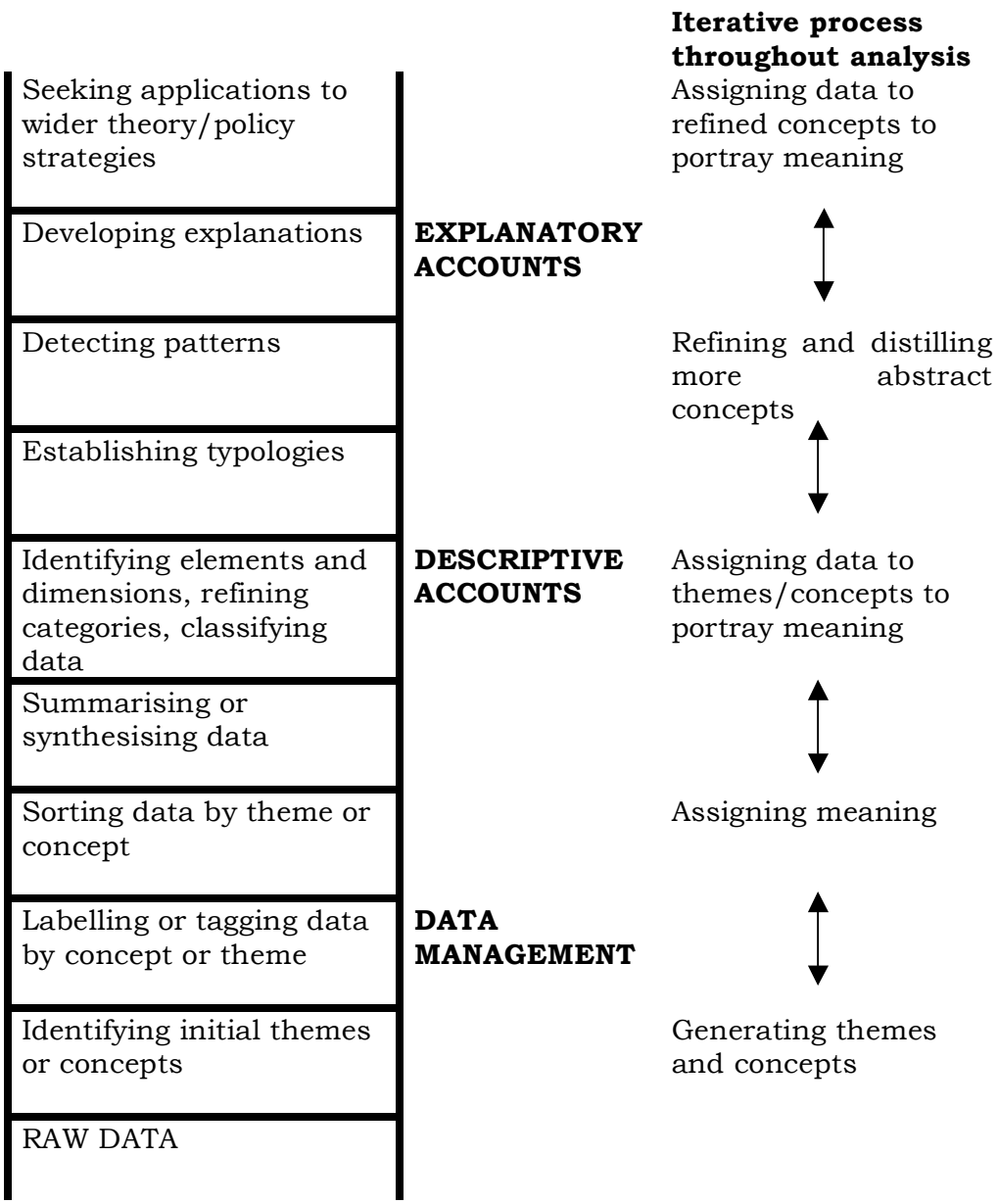
3.7.2 Audit

Descriptive data (proportions) were obtained on rates of use of the tool in practice, where the denominator was the total number of cases that should have been screened and the numerator was the number of cases with confirmed use of the tool. Chi-squared tests were planned to examine putative associations between training attendance, use of the tool and placement outcomes (e.g. breakdown versus no breakdown during the 3-month pilot phase).

3.7.3 Interviews

An 'Analytic Hierarchy' approach (as described by Spencer, Ritchie & O'Connor, 2003; Ritchie, Spencer, O'Connor, 2003) was used to create a thematic framework with which to categorise and sort the data from the interviews with social workers into key themes and concepts. This qualitative analysis method is widely used in qualitative research and enables data to be systematically organised in a rigorous and transparent way. It also facilitates movement between different levels of abstraction (represented by the ladder) so that the raw data is always kept in mind (see figure 2).

Figure 2: Stages and processes involved in the Analytic Hierarchy (Ritchie & Spencer, 1994)



The first stage (data management) involved sorting and reducing the data by identifying recurring themes and assigning labels to the data to build a thematic framework. In the second stage ('descriptive accounts') the range and diversity of each theme was specified and these were then grouped into categories. In the third stage: (explanatory accounts) patterns were described and reflected on to understand and explain their occurrence.

4. Results:

4.1 Training

In total 83% of those who attended the training (n=43) completed the WDECEF.

4.1.1 Descriptive statistics

Data from items 1-8 on the WDECEF were analysed using descriptive statistics. These are provided below in table 1.

Table 1: Descriptive statistics for items 1-7 on the WDECEF.

Item	Mean	Median	Standard Deviation (*sd*)
Q1. How well did the event meet its objectives?	1.9	2	0.58
Q2. How useful did you find the course content?	1.8	2	0.53
Q3. How relevant was the course to your job?	1.7	2	0.60
Q4. How would you rate the training delivery?	1.8	2	0.67
Q5. How well were diversity issues dealt with?	2.4	2	0.86
Q6. How would you rate the support materials?	1.8	2	0.68
Q7. How would you rate the venue for its facilities?	2.4	2	0.77
Q8. Were the refreshments adequate?	2.7	3	0.88

Most aspects of the training captured by items 1-8 of the evaluation form were predominantly rated as 'Very good' (items 1-6). Items 7 and 8 were predominantly rated as 'Satisfactory'.

The most positively endorsed aspect of the training was its relevance (mean =1.7, sd=0.6). The second most positively endorsed aspects of the training were its content (mean=1.8, sd=0.53), delivery (mean=1.8, sd=0.67) and support materials (mean=1.8, sd=0.68). Next was the training objectives (mean=1.9, sd=0.58). The least positively endorsed aspects of the training were the venue (mean=2.4, sd=0.77), the extent to

which diversity issues were addressed (mean =2.4, sd=0.86), and lastly the refreshments (mean=2.7, sd=0.88).

4.1.2 Analysis of themes

Table 2: Themes and frequencies of related responses (n) for Item 9.

Q9. What was the most useful part of the course for you?	
Theme	**n**
"Practice"	20
"Reflection"	14
"Tool"	12
"Everything"	7
"Delivery"	2
"Relevance"	1

Qualitative responses to item 9 were distilled into 6 themes; Practice", "Reflection", "Tool", "Everything", "Delivery", and "Relevance" (see Table 2).

Most responses to this item related to the theme of "Practice". In total 20 social workers reported the best part of the training was the opportunity to practise using the tool with the case-studies.

The next most frequent them related to "Reflection". More specifically 8 social workers reported that they had most enjoyed the group discussions. A further 6 social workers reported that they had most enjoyed thinking about the factors which impact on placement breakdown.

The third theme for this item related to the "Tool". 12 social workers reported that they most enjoyed learning how to use the tool.

The fourth theme for this item was "Everything". 7 social workers reported that everything about the training had been helpful.

Two final themes for this item related to the "Delivery" (n=2) of the training and the "Relevance" of the screening tool to their practice (n=1).

Table 3: Themes and frequencies of related responses (n) for Item 10.

Q10. What recommendations would you make to improve the course?	
Theme	**n**
"Nothing"	26
"Attendees"	6
"Tool development"	4
"Information"	4
"Other"	3

The responses to item 10 were distilled into 5 themes; "Nothing", "Attendees", "Tool development", "Information" and "Other".

Most responses to this item related to the theme of "Nothing". In total 26 social workers reported that there was 'nothing' they could suggest to improve the training.

The second most frequent related to "Attendees". Within this 4 social workers said that the other teams should have been invited to the training. A further 2 social workers said that 'all social workers should receive this training'.

A third theme related to "Tool development". More specifically 2 social workers said they would like the opportunity to review the screening tool before it was finalised. A further 2 social workers made suggestions about how the screening tool could be further developed. One social worker suggested developing the tool so it could be used with 'older children'. Another suggested expanding the tool to incorporate 'family factors' relevant to placement breakdown.

A fourth theme related to "Information". Within this 2 social workers said they would have liked more information about how to apply the tool to placements for children with a disability. A further 2 social workers said they would have liked more information about the research underlying the tool and the process of its development.

The final theme for this item was "Other". Within this theme 1 social worker said they thought the venue for the training could be improved, another social worker said they would have preferred 'less discussion', and another that they would have liked 'more time to practise using the tool'.

Table 4: Themes and frequencies of related responses (n) for Item 11.

Q11. How will you apply your learning at work?	
Theme	**n**
"Assessment"	20
"Supervision"	12
"Sharing knowledge"	8
"Reflection"	4

The responses to item 11 were distilled into 4 themes; "Assessment", "Supervision", "Sharing knowledge", and "Reflection".

The most frequent response to this item related to the theme of "Assessment" (n=20). More specifically the social workers reported they would use the screening tool to assess the risk of placement breakdown.

The second most frequent theme related to "Supervision" (n=12). More specifically the social workers reported they would use and discuss the screening tool during their supervision.

A third theme for this item related to "Sharing knowledge" (n=8). Within this, 6 social workers reported they would share the outcome of the tool

with the associated Foster Carer. A further 2 social workers reported that they would share the tool with their colleagues.

A final theme for this item related to "Reflection" (n=4). Within this, 2 social workers reported that they would use the screening tool to help them reflect on placements at risk of breakdown. A further 2 social workers reported that they would use the screening tool when discussing cases within their team.

4.2 Audit

4.2.1 Use

In total the electronic case notes for 73 11-13 year olds were audited to establish how many screening tools had been used during the 3-month pilot phase. This audit found evidence that 1 screening tool was used. In this case the screening tool had been completed and uploaded on to the electronic records system. There was no evidence that the tool had been discussed in supervision, or that the steps suggested by the guidance notes were pursued.

4.2.2 Impact

The intention was to test for associations between training attendance, use of the tool and placement outcomes. However, given that there was so little evidence of use it was not feasible to analyse these. Nevertheless to contextualise the other findings the frequencies of recorded PSMs and placement moves (or breakdowns) during the pilot phase were audited. As table 5 summaries, the percentage of placement moves within this population (11-13 year-olds) during the 3-month pilot phase (2011-2012) was 9% and largely comparable to the same period in the 3 preceding years. In total there were 8 PSMs held during the pilot phase. However, none of these were for children aged 11-13.

Table 5: Numbers of 11-13 year-olds who moved in the 3-month audit period

Year	**Number (%)**
2011-2012	8 (9%)
2010-2011	3 (4%)
2009-2010	7 (10%)
2008-2009	6 (9%)

4.3 Interviews

The field notes taken during the interviews were transcribed and distilled into 4 core themes. These related to acceptability, feasibility and the perceived barriers and facilitators to using the screening tool. Each core theme and the sub themes subsumed within each are described in turn below. Figure 3 then depicts a formulation of how these themes may relate to each other and influence outcome.

4.3.1 Acceptability

"Content"

This theme related to comments about the acceptability of both the broad and specific content of the screening tool. In terms of the broad content of the tool, social workers commented positively on the overall headings featured in the screening tool. For example the headings were described as a 'good reminder', and helped to 'keep all the factors in mind'. The headings were also described as 'a good reminder of the protective factors, which can often be forgotten'. In terms of the specific content of the tool, several social workers commented negatively on the tool's lack of specificity. For example one social worker reported that it was 'hard to distinguish placements with higher need' from using the tool. Another social worker commented that 'many children will possess several of the risks included' and 'the same risk could affect different children differently'. Related to this social workers commented on how the tool

could be developed to improve its specificity and therefore acceptability. For example one social worker commented that it would be more helpful if the 'risks which were most risky were highlighted', and another if an 'overall indication of the severity of risk of breakdown' was given so that time and resources could be better focussed.

"Validity"

This theme related to comments about the validity of the screening tool. In particular the comments centred on its validity in terms of the factors included in the tool and its applicability to all foster care placements. For example one social worker noted that 'there are other factors that contribute to placement stability which aren't included, such as the matching process between child and carer'. Another reported that 'the tool isn't applicable to placements for children with learning disabilities'.

"Value"

This theme related to comments about the perceived value of the screening tool and PSMs. In terms of the screening tool some social workers commented negatively regarding its value. For example one social worker described the screening tool as 'redundant' and 'pointless' because 'individually we already have ways of managing and responding to risk'. In terms of the PSMs social workers were predominantly positive when commenting on their value. For example one social worker reported that 'placement support meetings are helpful and used by every member of the team'. Another social worker commented that 'the placement support meetings share responsibility and the burden of predicting and responding to risk'.

4.3.2 Feasibility

This theme related to comments about the feasibility of implementing the screening tool and the PSMs. In terms of the screening tool, social workers commented negatively regarding the feasibility of each stage of the process, which involves completing the screening tool, discussing it

in supervision, and implementing the associated recommendations suggested in the guidance notes. For example, several social workers commented that 'it's not feasible to complete the tool for every child' and suggested that instead it could be used selectivity with 'more risky children'. Another social worker commented that 'very risky placements can break down before you've had a chance to use the screening tool'. In terms of the feasibility of the other stages, one social worker commented that 'it isn't feasible to discuss each child in supervision', and another said that 'implementing the recommendations laid out in the guidance notes is difficult as resources are limited'. In contrast, the feasibility of implementing a PSM was viewed positively. For example one social worker said 'calling a placement support meeting is easier than completing the tool' as the latter requires 'consulting with other professionals just to be able to complete it'.

Barriers

"Resistance"

This theme related to comments about resistance towards change. In particular the comments centred on a resistance towards the tool and the introduction of new processes more broadly. For example, one social worker described the process of using the screening tool as 'alien', compared to existing processes which felt 'automatic and intuitive.' Another said that 'you need to experience using and gaining benefit (from the tool) to change habits'.

"Burden"

This theme related to comments about workload burden. In particular the comments centred on perceptions of their current workload and ability to prioritise the tool. For example, one social workers described their current workload as 'overwhelming' and so 'there is a tendency to go for the easiest option'. Others commented that 'we feel expected to do everything' and that 'we already have lots of forms to complete'. A further

social worker commented that 'our workload has been very high so it has been difficult to prioritise the screening tool'.

Facilitators

"Sharing responsibility"

In terms of sharing responsibility for improving placement stability one social worker commented that 'placement stability is others responsibility too'. Another similarly commented 'placement stability is not just our responsibility and should be shared and fostered within a team'. A further social worker commented that 'it is not just the responsibility of social workers and the IRO to consider and manage placement stability. The onus should also be on the foster carer's and supervising social workers'.

In terms of sharing responsibility for completing the tool one social worker commented that 'it should be the IROs responsibility to complete the tool'. Another said 'the supervising social workers should complete the tool with foster carers as they have the most knowledge about the stability of a placement'. A further social worker asked 'could the foster carers not complete the tool initially?'

In terms of sharing responsibility for receiving training in how to use the screening tool, one social worker commented that 'more managers and supervising social workers should have attended the training so they could have the knowledge too'. Another social worker commented 'they (foster carers) should also have the training and knowledge in order to empower them to contribute to the stability of a placement'.

"Reminders"

This theme related to comments about the need to give reminders to use the tool in order to reinforce its use and its value. All the social workers interviewed commented that use of the screening tool had not been 'mentioned', 'prompted' or 'emphasised as a priority' since the training

session. One social worker commented 'we need managers to actively chase and prompt when initially rolling something out' as 'this reinforces its importance'. Another said 'any new procedure needs to be reinforced'. A further social worker commented that 'the managers should prompt using and thinking about the tool' and 'the tool should be discussed in team meetings and supervision'.

"Mandated use"

Social workers commented that 'if the tool was mandatory it might be used more' and 'the tool isn't mandatory at the moment and would need to be to increase its use'. In relation to incorporating the tool one social worker commented 'the tool could be incorporated an existing mandatory episode on Framework, such as the risk assessment'. Another social worker similarly commented 'you could incorporate the tool into the risk assessment tool. This is mandatory, but only focuses on some of the risks identified in the tool'.

5. Discussion:

5.1 Summary of aims and findings

This service project set out to evaluate the use, impact and perceptions of the STABILITY screening tool and it's training by social workers working in the Children and Young Peoples Service (CYPS). Although the feedback from the STABILITY screening tool training was largely positive, this alone was not sufficient to initiate the social workers to use the screening tool in their practice. Of the 73 11-13 year olds whose case notes were audited only 1 completed screening tool was found. Whilst this finding may reflect specific challenges associated with the local authority and/or intrinsic limitations of STABILITY, Munro's (2012) recent review of wider social work practices describes the majority of social work tasks as bureaucratic and crisis-led. This type of widespread practice culture is likely to impact on the attitudes, subjective norms and perceived behavioural control of social workers, which in turn could hinder behavioural change. Researchers studying behaviour change argue that in order to "bridge the gap" between the evidence-base and professional practice a clear understanding of the barriers and facilitators to achieving change in practices is required. Therefore, this discussion will focus on seeking to understand the factors that may have precluded the screening tools use and that might facilitate its use in the future. To do this, the themes that emerged from the interviews with the social workers will first be considered.

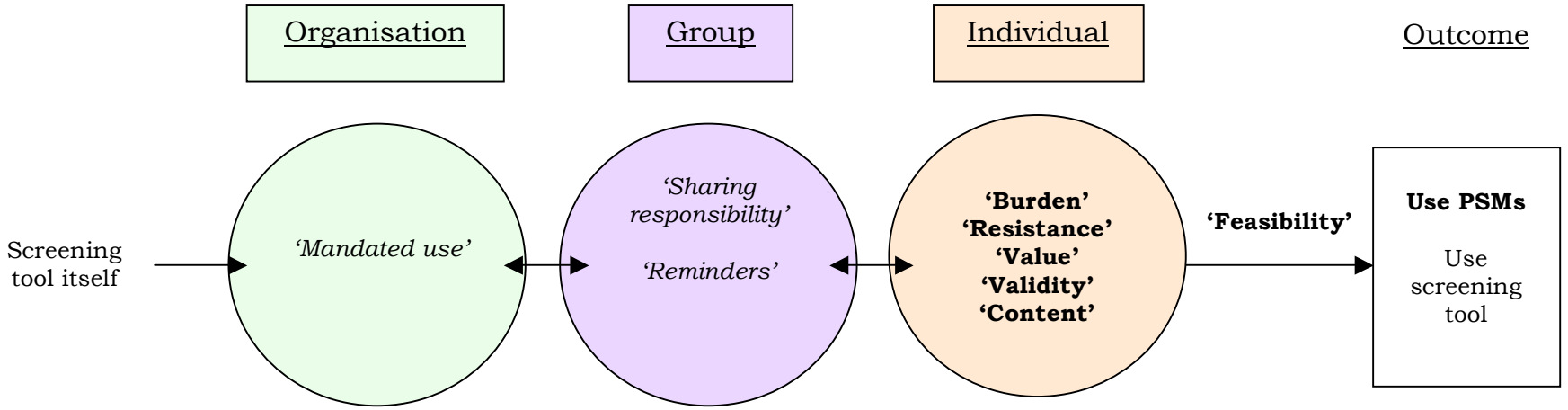
The themes that emerged from the interviews provide an insight into the social worker's perceptions of the acceptability and feasibility of, and barriers and facilitators to using the STABILITY screening tool. The model depicted in Figure 3 provides a conceptualisation of how these themes relate to each other and influence outcome. A key finding of this evaluation was that whilst social workers were not using the screening tool they were using the PSMs. This model also seeks to explain this difference in outcome, and in doing so identify what changes might need to occur to increase the screening tools use. The themes featured in italic

text are the 'facilitators' which if implemented might impact the themes in bold and lead to a change in outcome.

Given the themes identified, one explanation of why the social workers did not use the screening tool is because largely they held negative attitudes regarding its acceptability. This lack of acceptability may in turn have created resistance to its use and heightened perceptions of burden when social workers where asked to envisage using the tool. This sense of resistance and burden could then have negatively affected the perceived feasibility of the tool and so led to its very low uptake. In contrast, the social workers attitudes towards to the PSMs were largely positive and it was perceived as an acceptable intervention. The perceived acceptability of PSMs may in turn have dampened resistance and perceptions of burden and therefore positively affected the perceived feasibility of using a PSM.

Thus leading to a tendency to select this intervention over the screening tool. Furthermore, it is plausible that by implementing the 'facilitators' identified by the social workers that the acceptability and feasibility of using the screening tool could be improved, and the current barriers reduced. For example, incorporating the tool into existing processes might signal its importance and together with increased reminders and reinforcement to use the tool, these would promote its value and therefore reduce resistance. By sharing responsibility for its knowledge and use this might increase resources, reduce burden and therefore increase feasibility.

Figure 3: Formulation of the relationships between the themes and how these influence outcome.



5.2 Theories of behaviour change

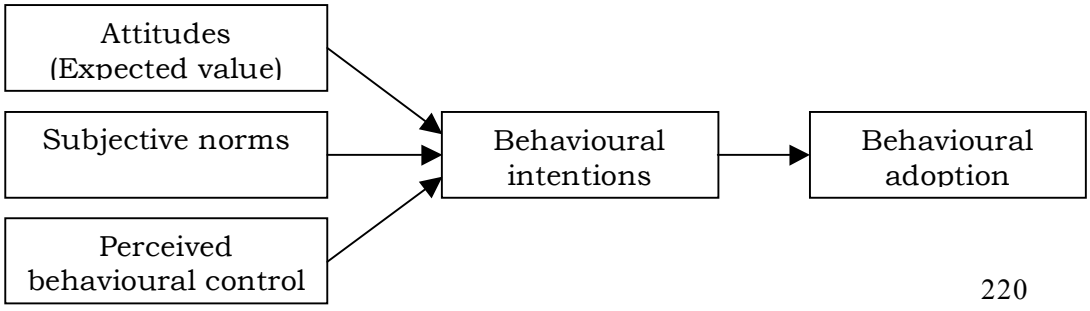
One way to evaluate the validity of this model and explanation is by considering previous theoretical work on behavioural change in organisations. Two well documented theories of behaviour change; the Theory of Planned Behaviour (TPB; Ajzen, 1991) and Diffusions of Innovations (DoI; Rogers, 2003) will be described in turn and discussed in terms of their crossover with the current findings.

5.2.1 Theory of Planned Behaviour (TPB)

The TPB states that an individual will carry out a behaviour if they have a strong intention to do so. It proposes that three variables (attitudes, subjective norms and self-efficacy) will affect the strength of an intention to perform any given behaviour (see Figure 4). The first variable 'attitudes' relates to the expected value of adopting a behaviour. The second variable 'subjective norms' refers to the degree of social pressure an individual is under to adopt a behaviour. The third factor 'perceived behavioural control' relates to the degree of self-efficacy the individual possesses to carry out the behaviour.

The factors highlighted in this theory closely overlap with the themes identified in this evaluation. For instance, based on the TPB the social worker's failure to incorporate the screening tool into their practice could be explained by their negative attitudes (i.e. low expectations of its value), a lack of social pressure (i.e. reinforcement and reminders from their co-workers and managers), and a lack of self-efficacy regarding the feasibility of incorporating the screening tool into their practice (due to perceptions of workload burden).

Figure 4: Ajzen's (1991) Theory of Planned Behaviour.



5.2.2 Diffusion of Innovations (DoI)

Rogers (2003) DoI theory seeks to explain why some interventions are adopted by a group of professionals whilst others are not. Rogers (2003) suggests five attributes that facilitate the uptake of an intervention and argues that these can account for between 49-87% of the variance seen in the adoption of new practices.

The first attribute 'relative advantage' suggests that in order for an intervention to be adopted individuals need to perceive it to be better than existing interventions. In the case of the CYPS a steady adoption of PSMs by social workers had already emerged before piloting of the screening tool began. Therefore in order for the screening tool to be adopted it needed to demonstrate a unique or relative advantage to promoting placement stability. In light of the critical views expressed by the social workers about the acceptability of the screening tool, it appears this wasn't achieved.

The second attribute suggests that for an intervention to be adopted it needs to be consistent with the values, needs and practices of the group. We know that the social workers perceived the screening tool to lack value and validity compared with the PSMs. The introduction of a new practice tool, which required careful reflection, and was not strongly mandated, also appears to have been inconsistent with the expectations and practices of the social workers. These apparent incompatibilities may account for the resistance described when considering adopting the screening tool. More positively though it might also suggest that if the tool were better incorporated into existing practices this might promote its value and importance.

The third attribute suggests that adopted interventions are those that are straightforward to apply. In line with this the social workers reported that they perceived calling a PSM to be easier than completing the screening tool. This may be because the PSMs share responsibility between professionals and therefore reduces time and personal burden.

The fourth attribute 'trialablity' suggests that interventions that can be experimented with are more likely to be adopted as this helps reduce uncertainty about change. The PSMs may again have proven preferential because they felt safer to experiment with than the screening tool. For example, the PSMs require multi-agency collaboration and so responsibility can be shared and their use more easily modelled by others.

The final attribute 'observable results' suggests that when the impact of applying an intervention is quick to see, this reduces uncertainty and increases the likelihood of it being adopted. In this case it is conceivable that the PSMs were more readily adopted because the joining together of professionals in a PSM can produce a quicker and more observable impact than the screening tool, which relies on the efforts of a single social worker.

5.3 Social care policies and guidelines

In line with NICE-SCIE (2010) recommendations the PSMs and STABILITY screening tool were intended to be used together to improve placement stability. However, the apparent preference among social workers to adopt PSMs over the screening tool could be viewed as understandable. For instance, although the STABILITY screening tool is theoretically useful to social work practice, the social workers may have felt better supported to manage the vulnerable and complex children on their caseload through using the PSMs. While the screening tool was designed to promote reflection on placement stability, arguably this is more difficult to do in isolation and may be better generated in a PSM where responsibility and burden are shared and professionals can reflect together and devise collaborative solutions.

PSMs require multi-agency collaboration as apposed to lone working, which is a shift emphasised by several key social care polices and guidelines. The Every Child Matters (ECM; DfES, 2003) document states the need for different professionals to work more closely together in order to achieve the five ECM well-being outcomes for children and young

people (being healthy, staying safe, enjoying and achieving, making a positive contribution, and achieving economic well-being). This key piece of legislation was born out of the Lord Laming inquiry, which revealed that poor inter-agency co-ordination and sharing of information was in large to blame for the tragic death of Victoria Climbié. Recent best practice guidelines for Looked After children and young people (NICE-SCIE, 2010) state that in order to provide effective care, professionals need to collaborate closely and share information. It recommends that multi-agency collaboration on complex cases is supported. The PSMs enlist this multi-agency collaboration and synthesise a range of skills and expertise, which can add value and help prevent placement breakdown. The Munro (2012) review of social work practice also encourages social work teams to be more reflective and to base their assessments on more face-to-face contacts and collaboration, which is again achieved through using a PSM.

5.4 Limitations

There were limitations to this evaluation, which should be highlighted when considering its findings and implications. Firstly, the length of the pilot for this intervention was brief (3-months), which may have led the potential use and impact of the screening tool to be underestimated. Secondly, the number of social workers interviewed was small (n=12). This may have impacted the generalisability and validity of the themes identified here. Thirdly, the social workers interviewed were recruited using an opportunistic sampling method and half of the sample did not attend the STABILITY training. This may have led to a biased sample or for the themes captured to be unrepresentative, although the responses of those who did not attend the training were not substantially more or less positive with regards to the STABILITY screening tool's acceptability or feasibility. Finally, because only 1 social worker attempted to use the STABILITY screening tool with a case it is difficult to evaluate the potential benefits and impacts of the tool on placement outcomes. It is therefore too early to argue that the tool should be implemented routinely and used with all cases. Notwithstanding these limitations the findings from this evaluation have important implications for the local authority

in terms of its future implementation of the STABILITY screening tool and drive to improve placement stability.

5.5 Recommendations

The joint consideration of the qualitative findings and existing theoretical literature on fostering successful behaviour change gives rise to six future recommendations.

5.5.1 Recommendation 1: Design a multi-level intervention strategy

Facilitating the adoption of evidence-based interventions requires a holistic and multi-level approach (Drake, Torrey & McHugo, 2003). The model depicted in figure 3 demonstrates that the factors to emerge from this evaluation span all three levels and interact to influence outcome. In the future this model could be used as a template to design a more effective intervention strategy for the screening tool. As described in section 5.2 the multi-level factors within the model could also be manipulated in order to increase the probability of the screening tool being adopted. For instance, by broadening the distribution of the training to relevant co-workers and managers (group level) this would increase resources, promote collaboration, widen responsibility, reduce burden and support the tools completion. By incorporating of the tool into existing practices (organisation level) this would enhance perceptions of value and improve feasibility by providing a framework of when to initiate and how to record use of the screening tool.

5.5.2 Recommendation 2: Improve uptake of training

Davis, Lindsay and Mazmanian (1994) propose that implementing a new intervention involves the relevant knowledge and skills must be made available to as many professionals as possible. Although the STABILITY training was mandatory its uptake was relatively low (35%). It will therefore be important that attendance at future training sessions is prioritised and encouraged by the management, and potential barriers (e.g. the location of the training) are considered to maximise attendance.

5.5.3 Recommendation 3: Prompt and reinforce use

The provision of training alone is not sufficient to bring about change in individual practice (Davis, Thomson, Oxman & Haymens, 1995), and needs to be followed up with reminders and reinforcement (Davis & Taylor-Vaisey, 1997). The social workers may have felt that using STABILITY was their responsibility alone if the management had not prompted its use. Reinforcing, prompting, and mandating use of the screening tool would signal the tools importance and that the effort taken to implement it is valued by the organisation. Therefore, if the STABILITY screening tool is rolled out again it will be important to place more emphasis on it being more management-led and perhaps target driven. For instance, senior social worker acting as supervisors could take responsibility for prompting discussion of STABILITY during supervision and then recording this on the electronic case notes of the LAC.

5.5.4 Recommendation 4: Identify and address specific obstacles

As with any group of professionals, social workers work within a specific social and organisational setting, which incorporates factors that may either bridge or widen the gap between evidence and practice. Davis et al. (1995) recommend conducting a 'pre-intervention' stage in order to determine the size of the gap between current and ideal practice and to illuminate the specific obstacles posed by the target group. In CYPS one way this technique could be incorporated is by developing the screening tool training to also identify and address attitudes, which may pose a barrier to the screening tools implementation.

5.5.5 Recommendation 5: Revise the name of the STABILITY screening tool

STABILITY is currently referred to as a "screening tool", which may be misleading as it suggests that it provides an indication of risk. However, the tool was not designed to 'screen' for placements at low, medium or high risk of breakdown. Rather its aims were to provide social workers with a structured assessment tool of risk/protective factors that could be

used to aid reflection on placements and assist with formulation, supervision and care planning. Therefore the local authority may wish to either revise the name of the STABILITY tool to minimise references to 'screening' or emphasise its purpose as a reflective tool. For instance it may be more accurate to refer to it as an "assessment," "care planning" or "practice improvement" tool.

5.5.6 Recommendation 6: Consider other uses for the STABILITY screening tool

The feedback gathered from the social workers revealed a mismatch in perceptions of the screening tools aim. The screening tool was originally designed to be a reflective tool, however, all the social workers approached commented that it would be more useful to them if the tool highlighted 'which risks were most risky' or gave an 'overall indication of the severity of risk of breakdown'. It may be that the social workers can reflect more effectively in a PSM, thus decreasing the need to promote the checklist as a reflective tool. In fact, the social workers may have highlighted how the screening tool could be developed to be more compatible with their practice needs (a factor known to important for organisational change; Rogers, 2003). Therefore as an alternative to 'Recommendation 5' the local authority might consider consulting with the creators of the screening tool to explore whether the tool could be developed to quantify risk.

5.5.7 Recommendation 7: Ownership

There is currently resistance by social workers to 'own' the adoption of the STABILITY screening tool. As discussed above this could be improved if negative attitudes regarding its value and validity were addressed, its use was positively reinforced and sharing knowledge and responsibility for its use reduced burden. Future research into and development of the STABILITY screening tool might also benefit from using a 'participatory' approach. Participatory research emphasises the importance of engaging affected groups (e.g. social workers and managers) in the research process and orientating research towards goals they perceive to be

beneficial to their practice (Minkler, 2000). The advantage of adopting this approach within the STABILITY project is that it could help to foster a sense of ownership for the screening tool among the social workers and improve perceptions of its validity, feasibility and relevance, thus increasing the likelihood of the screening tool being utilised (Wallerstein & Duran, 2006).

It may also be helpful to reconsider whether ownership of the screening tool may be helpfully assigned to another group within the CYPS such as CLAMHS. If success and value can be demonstrated at a smaller level this might then aid dissemination of the tool to other groups in the future.

5.5.8 Recommendation 8: Clarify the functions of the PSMs and STABILITY screening tool

It is evident that there is currently a preference to use PSMs rather than the STABILITY screening tool to promote placement stability. One potential explanation for this trend is that PSMs may be more compatible with the values and needs of the social workers and offer a relative advantage to prior practices. However, the use of PSMs is not clearly understood. For instance, little is known about how and when they are used, or their function, process, and impact on placement stability. Future research within the CYPS could aim to illuminate the respective functions of the PSMs and the STABILITY screening tool, so that their use and impact can be maximised.

5.6 Dissemination of STABILITY findings

The evaluation findings have been shared at the London Independent Reviewing Officers Conference and the Health Safeguarding Conference for LAC Health Professionals, who were interested in using the screening tool as part of their LAC medical assessments. A written summary of the findings will also be shared with the local authority and discussed with the Assistant Director of CYPS, who gave permission for the pilot of STABILITY.

5.7 Conclusions and summary

This service evaluation revealed that whilst most of the social workers that attended the training thought that placement stability was relevant to their practice, this did not lead to them using the STABILITY screening tool. Implementing new service innovations is a dynamic and evolving process. The research on behaviour change within organisations indicates that successful interventions are those that are continuously improved to better fit the needs of individuals and the services they work within. Interviews with the social workers revealed the barriers to its current use as well as clear suggestions to facilitate its use in the future. These were aligned with research and theory on successful behaviour change and gave rise to six future recommendations. If applied to future intervention strategies, these recommendations are likely to improve the acceptability, feasibility and subsequent utility of the STABILITY screening tool within the CYPS.

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Appendix 1: STABILITY screening tool

South London and Maudsley NHS
NHS Foundation Trust

KING'S College LONDON

S T A B I L I T Y
SCREENING TOOL

1. RISK FACTORS

	Rate (Y/N) if either of the following demographic risk factors apply.	Yes	No	Guidance reference
Child factors				
Age	Is the child aged over 12 years old?			1.1

	Rate the extent to which these potential risk factors affect, or have affected, the child. Rate each factor as Current if it applies in last 2 months, or Historic if it applies less recently (note: it is possible that both Current/Historic will apply for a given factor). If a factor is not applicable, please leave blank.	Current	Historic	Guidance reference
Child factors				
Externalising behaviour	Is the child displaying aggression, oppositional behaviour and/or offending?			1.2
Mental health problems	Is the child experiencing signs of depression, anxiety, psychosis and/or self-harm?			1.3
Abuse	Is there evidence of neglect, physical, emotional and/or sexual abuse?			1.3
Child's perception of placement	Is the child worried that this placement may be temporary (perceived or real)?			1.4
Experience of placement instability	Does the child have a history of unstable placements, i.e. breakdown of a longterm placement or has the child experienced multiple moves?			1.4
Experience of residential care	Has the child experienced residential care?			1.4
Birth family factors				
Parental substance misuse/alcohol abuse	Are birth parents misusing drugs or alcohol?			1.5
Criminality	Are birth parents involved in crime or in prison?			1.6
Death of parent	Has the child experienced the death of a parent or other caregiver?			1.7
Placement factors				
Siblings	Are the child's siblings placed separately?			1.8
Other foster children in placement	Are there any other foster children in the placement?			1.9

Appendix 1: STABILITY screening tool

Foster carers' own children	Are the foster carers' birth children within a 5-year age range of the child?			1.9
Carer factors				
Carer's expectations	Does the carer have unrealistic expectations of child (e.g. is the carer unprepared for behavioural problems, or expecting gratitude from child)?			1.10
Carer stress	Has the carer experienced stressful life events before or during placement?			1.11
Relationship factors				
Carer-social worker	Are there any difficulties in the relationship between yourself and the foster carer?			1.12
Child-carer	Are there any perceived difficulties in the relationship between the carer and the child?			1.13
Child-birth parent	Is the contact with parent(s) inconsistent, critical or negative (e.g. does the child express distress, confusion or disruptive behaviour, before or after contact)?			1.14

2. PROTECTIVE FACTORS

	As above, rate each factor as Current if it applies in last 2 months, or Historic if it applies less recently. If a factor is not applicable, please leave blank.	**Current**	**Historic**	**Guidance reference**
Child factors				
Education	Is the child achieving their potential at school/ college?			2.1
Social development	Does the child have good, meaningful friendships?			2.1
Leisure/interests	Is the child involved in activities that they enjoy?			2.1
Carer factors				
Carer family support	Does the carer have long-term partnership/mutual commitment from partners and other family members?			2.2
Social support	Does the foster carer have a developed social support networks (e.g. supportive friends, neighbours, colleagues)?			2.2
Carer parenting ability	Has the carer been able to develop effective parenting skills?			2.3
Relationship factors				
Role models	Does the child have contact with positive, non-family role models (e.g. youth leader or sports coach)?			2.4
SW continuity	Has the child had ≤2 SWs in the first 3 years of care?			2.5
Positive child-SW relationship	Has the child been able to develop a positive working relationship with you?			2.5
Positive child-carer relationship	Has the child been able to develop a positive relationship with their carer?			1.13
Managed contact with birth family	Is contact with parents, siblings and/or extended family arranged and attended?			1.14

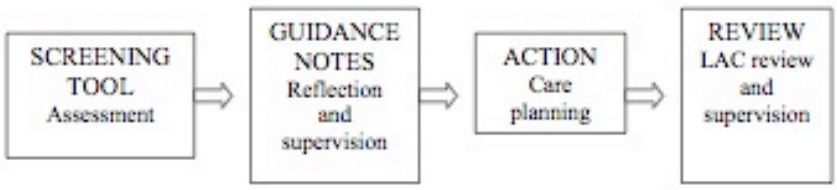
Appendix 2: STABILITY guidance notes

South London and Maudsley NHS
NHS Foundation Trust

KING'S College LONDON

S T A B I L I T Y
GUIDANCE NOTES

These guidance notes are designed to be used in combination with the STABILITY Screening Tool. They are intended to provide a framework for social workers to assess and think about placement stability in the context of care planning and supervision.



In each section of the guidance notes, recommendations are provided to assist in the planning of interventions that are likely to affect the stability of a placement. The suggested action points correspond to specific stability factors that may be influenced by social workers.

The term "foster carer" has been used throughout the guidance notes to represent any adult providing care for the child or young person (collectively referenced here as "child"). It is hoped this guidance will benefit foster carers, kinship carers, residential workers and keyworkers alike.

Contents

consultation to Young and Safe may be appropriate (extension 62159). Also consider a referral to the Risky Behaviour Panel or the YOS Risk Management Panel.

Does the foster carer have any concerns about potential risks to themselves or their family?

Action: If yes, this can be a trigger for ending placements. It is therefore important to give foster carers the opportunity to voice any misgivings about the child's behaviour. Careful planning around risk management can give the foster carer confidence in managing risky behaviour. Also consider a Placement Support Meeting (chaired by the child's IRO) to allow for strategic planning about placement needs (extension 68521).

1.3 MENTAL HEALTH PROBLEMS/ABUSE

If a child has a past/present history of mental health problems, or a history of abuse/neglect, then consider:

Have they been in contact with CAMHS or CLAMHS previously?

Action: If not, a referral to these services could help the child to access psychological assessment and treatment that improves their functioning and quality of life. The foster carer can also access support from CLAMHS in relation to their child.

Does the child have undiagnosed or not yet assessed special educational needs, communication difficulties and/or cognitive deficits?

Action: If you believe this is a possibility, check Framework for previous assessments and then contact CLAMHS or the child's school for advice and discussion.

For further consideration: There are strong links between unresolved experiences of trauma/childhood abuse and future mental health difficulties, as well as problems in building and maintaining relationships.

1.4 CHILD'S PERCEPTION OF PLACEMENT

To promote positive relationships between a child and their foster carer(s), consider:

If the placement is recent, how does the child feel about being in a new placement? Are they detached/pessimistic OR hopeful/looking forward to a fresh

start?

Action: A child needs to feel safe in order to settle; clear information should be shared with the child about their arrival and permanence. How this is done will depend upon their age and understanding. Detailed information should also be provided to the foster carer, so that they are well informed about a child's needs and potential difficulties that may arise during the placement.

For further consideration: A clear placement plan will aid the foster carer in providing effective care.

Has the child moved school and/or moved away from their friends at the same time as changing placement?

Action: If yes, plans for maintaining positive contacts with their social network may increase the child's commitment to the placement (e.g. encouragement to write letters or cards to their friends in previous schools).

To what extent does the child feel a part of the foster family?

Action: Prompting foster carers to organise family meetings and take a generally warm, inviting and inclusive approach may strengthen a child's sense of safety within a new family. A child's loyalty to their birth family is also likely to affect their commitment, and should be discussed with the child, birth parent(s) and foster carer(s).

Has the child experienced residential care?

Action: Children and young people who have had experience of residential care often experience multiple placement moves. This can be because they are having a planned move into semi-independence, but can be because they find it hard to settle in a placement and push boundaries. They may benefit from an increase in one-to-one hours with a specialist keyworker who has experience of supporting hard-to-reach young people with complex needs. They are also likely to benefit from a social worker who is very active and consistent in engaging them in education and other agencies.

BIRTH FAMILY FACTORS

1.5 PARENTAL SUBSTANCE MISUSE/ALCOHOL ABUSE

If the birth mother was misusing substances while pregnant, it is possible that the child might have neurodevelopmental problems. While not directly related to placement stability itself, these kinds of difficulties may present problems for the child and their foster carer(s). Consider:

Is there evidence that a child's mother had substance abuse problems during pregnancy?

Action: If yes, seek specialist advice from the LAC Medical team (0203 049 5974), CLAMHS (extension 68562) or CAMHS Neurodevelopmental Team (0203 049 5260) so that neurodevelopmental problems can be identified and appropriate interventions can be discussed.

Does parental substance misuse impact on contact?

Action: If yes, this may need to be addressed with legal services and the contact supervisor.

1.6 CRIMINALITY

While it is not possible to influence these factors directly, careful planning can prevent/reduce these risk factors from affecting placement stability. Consider:

For older children/teenagers, do they have access to a mentor?

Action: If not, consider options for mentoring and other means of promoting involvement in valued activities, which are known to be protective against placement breakdown. For young people whose families have links with gangs, or are involved themselves, consider a consultation with Young and Safe (extension 62159).

1.7 DEATH OF PARENT

Consider:

Is the child showing signs of unresolved grief?

Action: Discussion with CLAMHS duty may be indicated. There is also a national bereavement service which offers advice about loss. This is called Cruse and

information about local services can be found at
http://www.crusebereavementcare.org.uk.

PLACEMENT FACTORS

1.8 SIBLINGS

The impacts of separation from siblings will vary between children. When a child has previously held a care-giving role, separation can be particularly distressing due to anxiety about their sibling's well-being. On the other hand, it may be appropriate to place siblings apart when one sibling poses a serious risk to the other(s).

If a child has been separated from their sibling, then consider:

Is the child satisfied with the frequency and quality of contact arrangements with their sibling(s)?

Action: If not, confusion or uncertainty about contact can be reduced by the child having clear guidelines about when and where sibling contact will take place. It may be necessary for this to be shared in an age-appropriate manner (e.g. visual calendar). Life Story work can help the child develop a clear narrative about their family history and can raise helpful questions about their brothers and sisters.

1.9 OTHER CHILDREN IN PLACEMENT

Other children being present at a placement can influence stability in a variety of ways, and will require careful planning on an individual basis. Consider:

Is there already another foster child in the foster home?

Action: The arrival of new foster children can be unsettling for a child who is already in the placement. It is important to have an open discussion with the foster carer about how a child has been in previous settings, so that the foster carer can plan ahead in regards to managing unusual or difficult behaviour, and anticipate potential impacts for newly arrived/previously settled foster children. If the new foster child is a baby, this can impact on the amount of time a foster carer is able to engage with the original foster child, and can raise anxieties for the foster child around being abandoned, replaced or less important.

Does the foster carer have any of their own children living at home?

Action: Encourage foster carers to prepare their own child(ren) and explain to them

how they have an important contribution to make. It can also be helpful for foster carers to discuss some of the challenges and benefits associated with another child joining their family (e.g. benefits: chance to make a new friend; challenges: sharing toys, being a role model and at times needing to take the back seat).

FOSTER CARER FACTORS

1.10 FOSTER CARER'S EXPECTATIONS

When foster carers have high or unrealistic expectations (e.g. in terms of the gratitude they receive from a child), and these expectations are not met, this can cause considerable distress, tension and can lead foster carers to end a placement. Consider:

What does the foster carer expect from the child? Are the foster carer's goals attainable?

Action: Discuss the foster carer's expectations about fostering in general, and this child in particular, exploring whether their expectations are realistic or accurate.

Is there a clear placement plan, and has it been reviewed?

Action: Regardless of the length of placement, consider whether it is a good match and raise any concerns in supervision.

What does the foster carer need to know about possible behaviour difficulties in order to manage them more effectively?

Action: If the foster carer needs assistance with managing the child's behaviour, their Supervising Social Worker will be best placed to provide advice and guidance. If the difficulties are more complex, you may want to consider a referral to CLAMHS for Fostering Changes or further training via the Fostering Agency/Team.

1.11 FOSTER CARER STRESS

Stressful life events can impact negatively on a foster carer's mental health, or otherwise impair their motivation/ability to look after the child(ren) in their care. Consider:

Has the foster carer experienced significant stressful life events before/during the placement?

Action: If yes, discuss with foster carers whether they might require additional support (e.g. from their link worker, accessing respite care). If there are adverse changes in a foster carer's personal circumstances, this may warrant a Placement Support Meeting chaired by the child's IRO. The extent to which foster carers are open about difficulties may be dependent upon the quality of the relationship with the social worker or Supervising Social Worker.

RELATIONSHIP FACTORS

1.12 FOSTER CARER – SOCIAL WORKER

To develop and maintain a purposeful working relationship with a child's foster carer(s), consider:

Does the foster carer appear satisfied with our working relationship?

Action: Ensure that the foster carer's efforts are sensitively recognised, appreciated and positive contributions are reinforced. Provide opportunities for feedback on the quality of your working relationship. Discuss any difficulties in the relationship within supervision, and agree a plan for them to be discussed in an open and constructive way with the foster carer.

Is the foster carer's work deserving of formal recognition?

Action: Consider recognising a foster carer's good work by nominating them for a foster carer award facilitated by the Lambeth Adoption and Fostering Service.

1.13 FOSTER CARER – CHILD

The relationship between the child and their foster carer is fundamental to placement stability. Ultimately if the child feels safe and important, the placement is more likely to contain any difficulties that arise rather than buckle under the pressure. Some points to consider:

Does the foster carer spend enough quality time with the child? Is the foster carer-child relationship defined by emotional warmth, understanding and clear boundaries?

Action: If not, the foster carer may benefit from further training and advice. This may require increased support from the Supervising Social Worker, Fostering agency Training, or possible referral to Fostering Changes via CLAMHS.

1.14 CHILD – BIRTH PARENT

Difficulties in contact between the birth parent(s) and foster child can be distressing to the child and also create relationship difficulties with the foster carer. Consider:

Are there any difficulties around contact with the birth parent(s) (e.g. related to parental mental health, substance misuse, parent's relationship with social care, inconsistent and unreliable attendance, deliberate sabotaging of the placement)? Does the foster carer know how to manage with these difficulties sensitively with the child?

Action: Develop the foster carer's awareness of the potentially damaging effects of discussing conflicts in front of the child. Life Story work can help the child develop a coherent narrative about their past and why they are in care.

Does the foster carer have relevant knowledge about parental mental health without breaking the parents' confidentiality?

Action: Discuss any needs with the Supervising Social Worker and foster carer.

Are there any differences in the child's behaviour pre- and post-birth parent contact?

Action: Review observations made by the contact supervisor, looking for indications that the child may be distressed by contact with parent(s). Share any concerns about contact with your department practice manager or your supervisor.

2. PROTECTIVE FACTORS

CHILD FACTORS

2.1 BUILDING A CHILD'S RESILIENCE: EDUCATION, SOCIAL DEVELOPMENT AND LEISURE/INTERESTS

Participation in education and valued leisure/vocational activities can not only strengthen placements, but can also build a child's resilience and independence. Therefore consider:

Does the child have sufficient opportunities to access leisure activities?

Action: If not, provide information and facilitate engagement with after-school clubs, local authority organised activities and non-school clubs. Discuss how the foster carer can help the child to positively engage in and sustain involvement in activities. The foster carer may need to join the child initially.

For older children, are there any vocational opportunities in which s/he is interested and could be supported?

Action: Provide information about suitable opportunities, and consider whether any specific support/liaison may be required in order to facilitate attendance.

To what extent is the child participating and achieving in education?

Action: Work with the foster carer and liaise with education providers to obtain an accurate impression of a child's academic abilities and attainment. Ensure that the foster carer and child have agreed a set of achievable goals for educational attainment, with a plan to celebrate when these goals are reached.

Are there any unidentified educational needs that would benefit from further assessment or support?

Action: Consult with the child's teacher to ensure educational support is in place and is being used effectively. Confirm that the child's Personal Education Plan is up to date, or in need of reviewing. Consider indications for a Statement of Special Educational Needs.

FOSTER CARER FACTORS

2.2 FOSTER CARER FAMILY SUPPORT/SOCIAL SUPPORT

Appendix 2: STABILITY guidance notes

Social support from within and outside foster families can strengthen placement stability. Consider:
Does the foster carer/family have adequate social support? **Action:** Some foster carers can find it difficult to seek support in case it might be perceived as a sign of not coping. If this is thought to be the case, emphasise the importance of maintaining/building social support networks. This can be accompanied with information about foster carer networking and peer support groups (e.g. Lambeth FC, Independent Agency groups, BAAF). The Fostering Network national website is a useful resource for various aspects of foster carer support http://www.fostering.net **Does the foster carer have a supportive partner?** **Action:** In placements with two foster parents, consider ways of ensuring that the foster carers feel supported by one another. In particular, promoting the involvement of male foster carers can be of considerable importance in providing male role models for foster children.
2.3 FOSTER CARER'S PARENTING ABILITY Positive parenting skills (e.g. effective boundary setting, communication, use of praise and rewards) are likely to strengthen a placement. Therefore consider:
Is the foster carer inexperienced or otherwise seeking to develop their parenting skills? **Action:** If yes, Lambeth and partner agencies provide training around the needs of LAC and foster carers. Options include in-house training, agency training accessed via Supervising Social Workers and Fostering Changes run by CLAMHS.

RELATIONSHIP FACTORS

2.4 ROLE MODELS Positive role models can boost a child's confidence by providing encouragement, structure and friendship. This type of relationship can also support the stability of a placement.
Does the child have access to positive role models?

Action: If not, consider referral to local community organisations, after school clubs and local authority organised activities that can provide opportunities for children to come into contact with positive role models.

2.5 POSITIVE CHILD-SOCIAL WORKER RELATIONSHIP

The quality of the direct relationship between a social worker and child can also make an important difference to placement stability. A consistent relationship with a social worker, characterised by openness, reassurance, reliability and kindness, is likely to promote a child's sense of importance and self-confidence. The child's beliefs about entry into care can also influence the quality of this working relationship. Therefore consider:

To what extent does the child appear motivated to engage with me?

Action: Including the child in decision making, offering explicit reassurance, and demonstrating acts of kindness can all contribute to developing a good relationship with a foster child. Overt criticism and disagreements will undermine the relationship.

Are the child's beliefs about entering care impacting on our working relationship?

Action: A child who feels that they have been "given away", "taken away" or feel personally responsible for being in care may be less willing to engage. In such cases, continue with Life Story work to help the child develop a clearer understanding of why they are in care.

Has the child experienced multiple social workers?

Action: It is important to be empathic with the child and aware that it may be difficult for them to build a relationship with you due to having met many social workers. If you are moving on or the child is being allocated a new social worker, it is important that the ending or transition is marked with an event. This could be a card and/or outing.

Workforce Development Event Course Evaluation Form

Q1. How well did the event meet its objectives?

Outstanding	*Very Good*	*Satisfactory*	*Inadequate*
1	*2*	*3*	*4*

Q2. How useful did you find the course content?

Outstanding	*Very Good*	*Satisfactory*	*Inadequate*
1	*2*	*3*	*4*

Q3. How relevant was the course to your job?

Outstanding	*Very Good*	*Satisfactory*	*Inadequate*
1	*2*	*3*	*4*

Q4. How would you rate the training delivery?

Outstanding	*Very Good*	*Satisfactory*	*Inadequate*
1	*2*	*3*	*4*

Q5. How well were diversity issues dealt with?

Outstanding	*Very Good*	*Satisfactory*	*Inadequate*
1	*2*	*3*	*4*

Q6. How would you rate the support materials?

Outstanding	*Very Good*	*Satisfactory*	*Inadequate*
1	*2*	*3*	*4*

Q7. How would you rate the venue for its facilities?

Outstanding	*Very Good*	*Satisfactory*	*Inadequate*
1	*2*	*3*	*4*

Q8. Were the refreshments adequate?

Outstanding	*Very Good*	*Satisfactory*	*Inadequate*
1	*2*	*3*	*4*

Q9. What was the most useful part of the course for you?

Q10. What recommendations would you make to improve the course?

Q11. How will you apply your learning at work?

STABILITY Audit Proforma

Social worker ID:_____

LAC ID:_____

Has use of the STABILITY screening tool been mentioned in the notes? *Yes/No*

Has it been uploaded on to Framework? *Yes/No*

Has its use been discussed in supervision and documented on Framework? *Yes/No*

Has a Placement Support Meeting (PSM) called? *Yes/No*

Were any placement moves recorded? *Yes/No*

Notes:_____

_____

_____

_____

_____

_____

Interview Guide

Have you used the SATBILITY screening tool?

What factors affected whether you used/didn't use the STABILITY screening tool?

Have you called a Placement Support Meeting?

If yes, was this conducted in conjunction with information from the STABILITY screening tool?

What ideas do you have about how we can facilitate use of the STABILITY screening tool in the future?